Puritan Bennett 540™

Ventilator

User's Manual

COVIDIEN

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While the information set forth herein is believed to be accurate, it is not a substitute for the exercise of professional judgment.

The ventilator should be operated and serviced only by trained professionals. Nellcor Puritan Bennett LLC's sole responsibility with respect to the ventilator, and its use, is as stated in the limited warranty provided.

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Preface

Purpose of This Manual

This manual contains important information regarding the safe operation of your Puritan Bennett 540™ Ventilator. Your ventilator is an electrical device that can provide years of useful service with the proper care, as described in this manual.

Ensure that you read and understand the instructions contained in this manual before operating the ventilator.

WARNING

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, "Safety Information".

Qualification of Personnel

Installation and maintenance of the device must be made by authorized and trained personnel. In particular, training for the handling of products sensitive to electrostatic discharges must include the use of Electrostatic Discharge (ESD) protection devices and knowledge of the following symbol's meaning: , as well as using original spare parts and respecting quality assurance and traceability rules approved by Puritan Bennett.

Warranty

Information regarding your product warranty is available from your sales representative or Puritan Bennett.

Extended Service

The Puritan Bennett 540™ Portable Ventilator offers extended service contracts/warranties for purchase when the ventilator is purchased. Please contact your local Covidien/Puritan Bennett Sales or Service Representative for additional information.

For online technical support, visit the SolvIT[SM] Center Knowledge Base by clicking the link at http://www.puritanbennett.com. Here, you will find answers to frequently asked questions about the Puritan Bennett 540™ Ventilator and other Puritan Bennett products 24 hours a day, 7 days a week. If you require further assistance, contact your local Puritan Bennett representative or call Puritan Bennett Technical Support at 1.800.255.6774.

1 Safety Information

1.1 Definitions

This manual uses three indicators to highlight critical information: Warning, Caution, and Note. They are defined as follows:

WARNING
Indicates a condition that can endanger the patient or the ventilator operator.

Caution
Indicates a condition that can damage the equipment.

Note:
Indicates points of particular emphasis, that make operation of the ventilator more efficient or convenient.

It is essential to read, understand and follow these instructions before using the Puritan Bennett 540™ Ventilator. In order to use the ventilator correctly and efficiently and to help prevent incidents, please pay particular attention to sections 1.2, "Warnings" and 1.3, "Cautions" as well as all warnings and cautions contained throughout this manual.

1.2 Warnings

General Precautions For Use

WARNING

- **Federal law restricts this device to sale by or on the order of a licensed physician.**
- **The ventilator must be used only under the responsibility and on the prescription of a doctor.**
- **The ventilator must be used according to its intended use. Refer to section 2.1, "Indications for Use".**
- **Be aware this manual describes how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.**
- **While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.**
- **To ensure that ventilation continues uninterrupted, ensure alternative power sources are available (AC power source, extra batteries, or an auxiliary DC car adapter). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.**
- **.Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of expiratory gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.**
- **The ventilator must not be used with flammable anesthetic substances.**
- **Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.**
- **You must start the ventilator and allow it to complete one full breath cycle prior to connecting the patient. Do not connect the patient before this cycle completes.**
- **.Due to its limited internal battery's reserve capacity, the ventilator should only be operated occasionally while powered by its internal battery. Ensure that the internal battery never becomes fully discharged.**
- **A ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient's caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.**
- **Before dispensing the ventilator to caregivers or the patient for home use, ensure the Locking Key is activated so that critical ventilator settings are not modified.**
- **Do not perform ventilator alarm tests while the patient is connected to the ventilator.**
- **Verify the functionality of the alarms conditions before connecting the patient to the ventilator.**
- **If the ventilator fails the alarm tests or if you cannot complete the tests, refer to chapter 3, "Alarms and Troubleshooting" or call your equipment supplier or Puritan Bennett.**
- **When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.**
- **A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, the ventilation will resume without having to press the VENTILATION ON/OFF button.**
- **To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.**
- **A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is recommended. Refer to chapter 7, "Cleaning".**
- **Handle the ventilator with care during and after use, particularly when room temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.**

General Precautions For Installation

WARNING

Environment:

- **Because the internal Lithium-ion battery of the Puritan Bennett 540™ Ventilator contains more than 8g (equivalent) lithium and has a power-rating greater than 100 Wh (watt-hour), it is categorized as Hazardous Material (Dangerous Good), Class 9- Miscellaneous, even though the ventilator meets current safety standards.**
  The ventilator, because of this categorization, is subject to strict transport conditions under the US Department of Transportation (US DOT) regulations for the transport of hazardous materials (49 CFR 173.185).
  As US DOT regulations cover commercial transportation only, there are two groups that can be exempted from these regulations. The first group consists of private individuals, providing that the goods are for their own personal use and measures have been taken to prevent leakage. The second group consists of persons that transport the goods because they need the product to execute their job(s). The later group is able to carry/transport certain hazardous materials, such as the Puritan Bennett 540™ Ventilator and the associated Lithium-ion battery(ies), under the established Materials of Trade (MOT) provisions detailed in 49 CFR 173.6. For any other group or purpose, transport must be compliant with the applicable Hazardous Materials/Dangerous Goods regulations specific to the origin/destination and mode of transport. Air transport of the Puritan Bennett 540™ Ventilator in only allowed as carry-on baggage, which may include up to two (2) individually packaged spare Lithium-ion batteries (it is recommended that users verify specific requirements/limitations with the airline carriers as to which measures to take before the voyage).
- **Even though the Puritan Bennett 540™ Ventilator meets current safety standards, the internal Lithium-ion battery of this device contains more than 8g equivalent lithium and exceeds a power-rating of 100 Wh (watt-hour) and therefore considered to be a Hazardous Material (Dangerous Good), Class 9 - Miscellaneous when transported in commerce. As such, the Puritan Bennett 540™ Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions established by the US Department of Transportation (49 CFR 173.185) as well as other international transportation regulations. This classification and regulatory requirements may vary depending upon the country and mode of transport. In addition, air transport of the Puritan Bennett 540™ Ventilator is only allowed as carry-on baggage, which may include up to two (2) individually packaged spare Lithium-ion batteries. (it is recommended that users verify specific requirements/limitations with the airline carriers as to which measures to take before the voyage).**
- **To minimize the risk of damage, you must use the ventilator Dual Bag to transport the ventilator.**
- **The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.**
- **To avoid damage to the ventilator, fluids must not be allowed to enter the device, particularly through the air inlet filter or the cooling apertures located in the side, rear, and bottom panels of the ventilator.**
- **To ensure correct and lasting operation of the device, ensure that the ventilator is installed and operated in the environmental conditions recommended in Appendix A, "Specifications."**
- **Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.**
- **Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.**
- **Do not place the ventilator in a position where a child can reach it or in any position that might cause it to fall on the patient or someone else.**
- **To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.**
- **If the ventilator has been transported or stored at a temperature that differs more than ± 36 °F (±20 °C) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least two (2) hours prior to use.**

WARNING

Environment (Cont'd):

- **If the room temperature where the device is operated is greater than 95 °F (35 °C), the flow supplied at the device outlet may exceed 106 °F (41 °C). This may lead to undesirable side effects for the patient. To avoid injury to the patient move the patient and the ventilator to a cooler location. For more information, contact Puritan Bennett.**
- **The default setting for altitude compensation is YES. Altitude compensation should always be set to YES for accurate volume delivery calculations at all elevations.**
- **To avoid a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.**
- **If the ambient temperature is above 104 °F (40 °C), the battery's thermal cut-off circuit may prevent the battery from recharging fully—even if the INTERNAL BAT charging indicator indicates the battery is completely recharged.**
- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see chapter 8, "Routine Maintenance"). This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.**
- **Handle the ventilator with care during and after use, particularly when room temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.**

Electrical Power Supplies:

- **Never connect your ventilator to an electrical outlet controlled by a wall switch because the power may be inadvertently turned off.**
- **For the AC ("mains") power cable to be properly secured, the attachment located on the power cable must be fitted into the power cable holder incorporated in the battery access cover and located under the AC (mains) power socket. Refer to section 4.2, "Connecting to External AC Power".**
- **The power supply to which the ventilator is connected (both AC and DC) must comply with all applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation. Refer also to the electrical specifications found in Appendix A, "Specifications".**
- **Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12– 30 VDC power source (via the DC power cable) does not enable charging of its internal battery.**
- **Due to its limited internal battery's reserve capacity, the ventilator should only be operated occasionally while powered by its internal battery. Ensure that the internal battery never becomes fully discharged.**
- **When using a car auxiliary adapter (cigarette lighter) ensure the car has been started prior to plugging in the ventilator's DC adapter.**
- **Even if the "INTERNAL BAT" indicator is off, charge of the battery may sometimes be incomplete regardless of charge time when the ambient temperature is above 104 °F (40 °C). This is due to the characteristics of the battery's internal heat safety device.**
- **When the "LOW BATTERY" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.**
- **When replacing the ventilator's internal battery, the ventilator must be disconnected from all external power supplies and turned off.**
- **Batteries should be disposed of according to environmental legislation in your country and locality.**
- **Never expose any batteries to direct flame.**
- **Never touch the ventilator's internal components, including the battery, and the patient simultaneously.**

WARNING

Hoses and Accessories:

- **The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits. High and Low VTE alarm parameters must be properly set to warn in the event of patient suffocation.**
- **During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming air. For this reason, the use of a humidifier, to minimize drying of the patient's airways and subsequent irritation and discomfort, must be used.**
- **If exhaled tidal volume or exhaled minute volume measurements are required to ensure correct patient ventilation a double limb patient circuit configuration must be used in order to detect leaks. In this case, both the High and Low VTE alarm parameters must be properly set to warn in the event of patient suffocation.**
- **The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection, and to minimize the risk of patient strangulation.**
- **For pediatric use, ensure that the patient circuit type fits, and, in all respects, is suitable for use with a child. Use a pediatric circuit for patients that weigh under 53 lb. (23 kg). See Table E-2, List of Circuits, on page E-2, for a list of recommended patient circuits.**
- **Resistance of the exhalation valve and accessories (water traps, filters, and so on) must be as low as possible.**
- **Adding attachments to the ventilator breathing system can cause the pressure during exhalation at the patient connection port to increase.**
- **The exhalation valve must allow rapid discharge of the circuit pressure. Ensure that the exhalation valve is always clean and its evacuation aperture (exhaust port) is never obstructed.**
- **Users must always possess an additional breathing circuit and exhalation valve while using the Puritan Bennett 540™ Ventilator.**
- **Consult with your Customer Support representative before attempting to use a heated humidifier.**
- **Always position a humidification device so that it is lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and periodically empty these water traps.**
- **If a heated humidifier is used, you should always monitor the temperature of the air delivered to the patient. Air delivered from the ventilator that becomes too hot may burn the patient's airway.**
- **Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.**
- **The level of inspiratory resistance of the circuit and accessories (bacteria filter, humidifier, and so on) must be as low as possible. Settings—particularly the LOW PRESSURE DISCONNECT alarm, High inspired volume (High VTI), and Low inspired volume (Low VTI) settings—must be periodically adjusted according to changes in the patient circuit resistance—especially when filters are replaced.**
- **To ensure proper performance of the ventilator, use a patient circuit recommended by Puritan Bennett in this manual; refer to chapter 4, "Installation and Assembly". The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 3.6 feet (1.10 meters) to 6.6 feet (2.00 meters).**
  The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.
- **When using non-invasive ventilation (niv), use a non-vented nose or face mask.**
- **Before using the Nurse Call system, ensure that its connections are secure and it operates properly. For more information, contact Puritan Bennett.**

Precautions Regarding Settings

WARNING

- **Before starting ventilation, ensure that the device is properly assembled and that the air inlet, cooling vents, and alarm sound diffusion holes are not obstructed. Ensure also that the patient circuit is of the proper configuration (double or single limb), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.**
- **Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of expiratory gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.**
- **Alarm volume should be adjusted with respect to the ventilator's operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused with the Alarm Pause function by pressing the ALARM CONTROL key twice once the alarm has been declared.**
- **Monitor the patient's state of health in order to ensure that the ventilator's settings are always suited to the patient's current physiological requirements.**
- **In the case of pediatric use, ensure that the adjusted tidal volume is compatible with the needs of the child.**
- **Ensure that the tidal volume setting in VC is compatible with the needs of the patient.**
- **Do not conduct the ventilator alarm test while the patient is connected to the ventilator. Switch the patient to an alternate means of ventilation before testing.**
- **If APNEA TIME is set to a value higher than 60/Control R then the APNEA alarm will not activate.**
- **Setting Alarm limits to extreme values can cause the ventilator alarms to malfunction.**
- **Adjustable alarms should not be systematically cancelled; instead, they should be adjusted according to the needs and condition of the patient.**
- **A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, the ventilation will resume without having to press the VENTILATION ON/OFF button.**

Maintenance Precautions

WARNING

- **Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your equipment supplier or Puritan Bennett.**
- **If you cannot determine the cause of a problem with your ventilator, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.**
- **Except for replacing the internal battery and cleaning the device, do not try to repair or otherwise service the ventilator yourself, or modify the ventilator, its components, or accessories. Doing so might endanger the patient, cause damage to the ventilator, and/or void your warranty. Only qualified service personnel should attempt repair of the ventilator.**
- **On a daily basis, ensure the proper connection and operation of the patient circuit.**
- **If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.**
- **After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.**
- **Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in Table 7-1.**
- **Do not attempt to repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only qualified service personnel should repair or service the ventilator.**
- **If the ventilator is damaged or its external housing is not correctly closed or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.**
- **The exhalation block is intended for single use by a single patient. It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously, trained personnel should clean the exhalation block periodically. The exhalation block should be changed every 3 months and cannot be reused with any other patient.**
- **Ensure that the exhalation block is completely dried after cleaning and prior to use.**
- **When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the expiratory flow sensor be recalibrated before the exhalation block is used; refer to section 10.1, "Calibrating the Expiratory Flow Sensor" in the Clinician's Manual.**
- **The patient circuit is intended for single use by a single patient and should be changed according to the manufacturer's recommendations. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator) and chapter 4, "Installation and Assembly".**
- **A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is recommended. Refer to chapter 7, "Cleaning".**
- **When replacing the ventilator's internal battery, the ventilator must be disconnected from all external power supplies and turned off.**
- **Never touch the ventilator's internal components, including the battery, and the patient simultaneously.**
- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see section 10, "Routine Maintenance in the Clinician's Manual). This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.**

WARNING

Maintenance Precautions (Cont'd):

- **For environmental protection, the ventilator and its components, whatever their respective conditions of operation, cannot be disposed of with household waste and must be submitted for suitable selective collection and possible recycling. Observe all applicable regulations when disposing of the ventilator and any of its components.**
- **If the device is damaged, its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.**
- **After replacing the ventilator's internal battery, push on the battery's cover from the rear towards the front to take pressure off the cover mounting brackets, thereby avoiding breakage when the screws are tightened.**

Precautions Regarding Oxygen

WARNING

- **The ventilator must not be used with flammable anesthetic substances.**
- **Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that excessive oxygen use is likely to lead to serious complications—including, but not limited to, patient injury.**
- **Strictly follow the instructions provided in section 4.8.2, "Connecting the Oxygen Supply", which include the use of a flow regulator and special coupler.**
- **To avoid injury to the patient and/or possible damage to the ventilator: before using the ventilator, use a flow meter (flow regulator) to regulate the oxygen supply to specifications before connecting the ventilator to the oxygen supply.**
- **The Puritan Bennett 540™ Ventilator does not include an oxygen analyzer. Always measure the delivered oxygen with a calibrated oxygen analyzer that features a high and low concentration alarm in order to ensure that the prescribed oxygen concentration is delivered to the patient.**
- **Ensure that the oxygen supply pressure to the machine never exceeds 7.25 psi (49.99 kPa) or a flow of 15 lpm. Refer to Table A-8 on page A-3 for volume and sensitivity tolerances.**
- **In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Air the affected room to bring the oxygen level down to normal.**
- **The hose connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.**
- **Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.**
- **The coupler must not remain connected to the oxygen connector unless it also connected to a leak-proof, external oxygen gas source. When an oxygen supply is not being used with the ventilator, disconnect the oxygen source completely from the ventilator.**
- **To prevent any interference with the internal sensors of the ventilator, do not install a ventilator humidifier upstream of the ventilator.**

1.3 Cautions

General Precautions For Use

Caution

- To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only qualified personnel should attempt to service the Puritan Bennett 540™ Portable Ventilator.

General Precautions For Installation

Caution

Environment:

- Avoid using the ventilator, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake and other filters.

Electrical Power Supplies:

- Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds.
- Do not store the internal battery, either installed within or removed from the ventilator, for more than two (2) years.
- To connect the ventilator to an external power source, first ensure the ventilator's **I/O** switch is off (**O**). Then, connect the desired power cable to the ventilator. Finally, connect the power cable to the external power source.
- To disconnect the ventilator from an external power source, first power-down the ventilator. Then, disconnect the power cable from the external power source and, finally, the ventilator.
- Do not leave power cables lying on the ground where they may pose a hazard.
- Ensure that the AC power cable is in perfect condition and not compressed.
- To connect the ventilator to a Nurse Call device, contact Puritan Bennett to check the ventilator's compatibility with the Nurse Call device and order a suitable connection cable. Do not use Nurse Call devices that operate based on the closure of an electrical circuit, because the devices often do not take into account possible cable disconnection or a total loss of power. Ensure that the Nurse Call device is always connected to the ventilator.

Caution

Hoses and Accessories:

- Before opening the packaging for the Patient Circuit, ensure that no damage is evident to the packaging or its contents. If evidence of damage exists, contact your supplier.

Maintenance Precautions

Caution

- Before cleaning the ventilator, first disconnect the ventilator and the circuit.
- Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.
- If the ventilator is used indoors, the condition of the air inlet filter should be checked monthly. If the ventilator is used outdoors or in a dusty environment, the filter should be checked weekly and replaced as necessary.
- The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.
- Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.
- Except for changing the battery (as required by qualified technicians or the Clinician), do not attempt to open the ventilator's enclosure. Doing so might result in damage to the device and/or may void your warranty.

Precautions Regarding Oxygen

Caution

- The oxygen supply hose ages even when it is not in use and should be replaced periodically. The exhalation date may be located on the back of the hose end-piece.
- The oxygen supply must be regulated using a flow meter connected to the source gas outlet.
- The oxygen supply must be shut off when ventilation is interrupted. Before disconnecting the oxygen hose, allow the ventilator to continue for a few cycles without oxygen to flush the patient circuit of excess oxygen.

Precautions Regarding Electromagnetic Interference

Caution

- The Puritan Bennett 540™ requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, "Specifications."
  In particular, the use of nearby mobile and portable communications equipment using radio frequencies, such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation;refer to section A.9, "Manufacturer's Declaration" in the Clinician's Manual.
- The use of any accessory other than those specified, with the exception of the power supplies or cables sold by Puritan Bennett, may lead to an increase in electromagnetic emissions or a decrease in the equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.

1.4 Symbols and Markings

Table 1-1. Ventilator Symbols

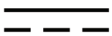
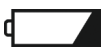
Symbols	Descriptions
	It is essential to read, understand, and follow these instructions before using the Puritan Bennett 540™ Ventilator (ISO 7000-0434A). This symbol appears on the ventilator's back panel, and internal battery; see Table 1-2, item 11.
	Type BF applied part (IEC 60417-5333). A regulatory standard classification for protection against electrical shock for the part of the device that contacts the patient. This symbol appears on the ventilator's back panel; see Table 1-2, item 6.
	Direct current, DC (IEC 60417-5031). This symbol appears on the ventilator's back panel; see Figure 1-4, item 10. Figure 4-5 on page 4-5
	Alternating current, AC (IEC 60417-5032). This symbol appears on the ventilator's back panel and keyboard; see Figure 1-4, item 9, and Figure 2-3 on page 2-5, item 10.
	Internal Battery. This symbol appears on the ventilator's keyboard; see Figure 2-3 on page 2-5, item 10.
	Insulation class II equipment (IEC 60417-5172). A regulatory standard classification for protection against electric shock. Class II equipment relies on double insulation rather than protective earthing. This symbol appears on the ventilator's back panel; see Table 1-2, item 6.

Table 1-1. Ventilator Symbols (Continued)

Symbols	Descriptions
IP31	Index of Protection rating for the ventilator's enclosure, defined in IEC 60529 (BSEN60529:1991). The first digit, 3, indicates protection against the intrusion of small foreign bodies (including fingers, tools, wires, etc. with a diameter greater than 2.5 mm) into the ventilator. The second digit, 1, indicates protection against water dripping or falling vertically, as well as an environment featuring water vapor condensation and/or light rain. This rating appears on the ventilator's back panel; see Table 1-2, item 6.
LR 58941 NRTL /C	CSA – Canadian Standards Association. This symbol appears on the ventilator's back panel; see Table 1-2, item 6.
	This symbol appears on the ventilator's front panel UP/UNFREEZE key; see Figure 2-3 on page 2-5, item 6. This key is used to: move the LCD display's cursor upwards, line-by-line; increase the value of displayed and selected parameter settings; restart ("unfreeze") waveforms tracing.
	This symbol appears on the ventilator's front panel DOWN/FREEZE key; see Figure 2-3 on page 2-5, item 5. This key is used to: move the LCD display's cursor downwards, line-by-line; decrease the value of displayed and selected parameter settings; stop ("freeze") waveforms tracing.
	This symbol appears on the ventilator's front panel ENTER key; see Figure 2-3 on page 2-5, item 4. This key is used to confirm command actions.
AUDIO PAUSED ALARM PAUSED	This symbol appears on the ventilator's front panel **ALARM CONTROL** key; see Figure 2-3 on page 2-5, item 3. This key is used to: cancel the audible portion of alarms for 60 seconds at a time; cancel an alarm. For more information, refer to section 3, "Alarms and Troubleshooting."
	This symbol appears on the ventilator's front panel MENU key; see Figure 2-3 on page 2-5, item 7. This key is used to access the ventilator's menus via the ventilator's front panel LCD display.
	This symbol (IEC 60417– 5009). appears on the ventilator's front panel VENTILATION ON/OFF button; see Figure 2-3 on page 2-5, item 8. This key is used to Start and Stop ventilation.
TO PATIENT	Air outlet towards patient. This symbol appears on the front right of the ventilator, adjacent to the TO PATIENT port; see Figure 1-3, item 2, and Figure 4-9 on page 4-9.
FROM PATIENT single patient	Air return from patient (double-limb option). This symbol appears on the front-left of the ventilator, adjacent to the From Patient port; see Figure 1-2, item 5.
Patient Press.	Patient proximal pressure port. This symbol appears on the front right of the ventilator, adjacent to the From Patient port; see Figure 1-1, item 4, and Figure 4-9 on page 4-9.
Exh. Valve	Exhalation valve pilot port. This symbol appears on the front right of the ventilator, adjacent to the TO PATIENT port indicating the connection of the tubing between the patient circuit exhalation valve; see Figure 1-1, item 4, and Figure 4-9 on page 4-9.
O_2 INLET	Oxygen inlet. This marking appears on the back panel of the ventilator, adjacent to the oxygen inlet port; see Figure 1-4, item 3, and Figure 4-14 on page 4-14.

Table 1-1. Ventilator Symbols (Continued)

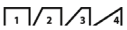
Symbols	Descriptions
	Nurse Call connector. This symbol appears on the back panel of the ventilator, adjacent to the nurse call connector; see Figure 1-4, item 3, and Figure 4-18 on page 4-18.
	Switch in "Off" position (IEC 60417-5008). This symbol appears on the I/O (power on/off) switch on the back panel of the ventilator to indicate the switch's "Off" position. See Figure 2-2 on page 2-4, item 2.
	Switch in "On" position (IEC 60417-5007). This symbol appears on the I/O (power on/off) switch on the back panel of the ventilator to indicate the switch's "On" position. See Figure 2-2 on page 2-4, item 2.
	Software Lock Enabled. This symbol appears on the upper-left of the ventilator's LCD display when the keyboard Locking Key is enabled.
	Internal Battery. This symbol appears on the top-center of ventilator's LCD display to indicate that the ventilator is being powered by its internal battery. See Figure 2-4 on page 2-6, item 1 and refer to chapter 6, "Internal Battery", for more information.
	Pressure rise times (inspiratory phase) parameter. These symbols appear on the ventilation mode menu screens. For more information, refer to chapter 3, "Operating Parameters". In pressure ventilation modes, you can select one of four rise times with setting 1 representing the fastest rise time and setting 4 representing the slowest.
	Flow shape ("flow distribution shape", inspiratory phase) parameter. These symbols appear on the ventilation mode menu screens; selectable for Vol A/C mode only. For more information, refer to chapter 3, "Operating Parameters". In volume ventilation modes you can select between Square (SQ) or Descending (D) flow patterns.
	Selected line (filled square). When making menu choices, this graphic indicates the line on which the cursor is currently positioned.
	Non-selected line (empty square). When making menu choices, this graphic indicates a line on which the cursor is currently not positioned.
	Locked parameter line. When making menu choices, this graphic indicates a line that cannot be selected (the Locking Key is enabled).
	Active parameter line. When making menu choices, this graphic indicates that the current parameter is selected and can be changed. See chapter 5, "Operating Procedures".
	Inspiratory Effort Detected. This symbol appears in the front panel display's Status window when the patient triggers a breath.
	Parameter adjustment bar. This graphic shows the current setting for parameters such as display contrast and alarm volume in the Preferences menu.
	WEEE (Waste Electrical and Electronic Equipment). This symbol means that this product must not be disposed of with household waste. Observe local ordinances for proper disposal. Refer to Table 1-2, item 6.

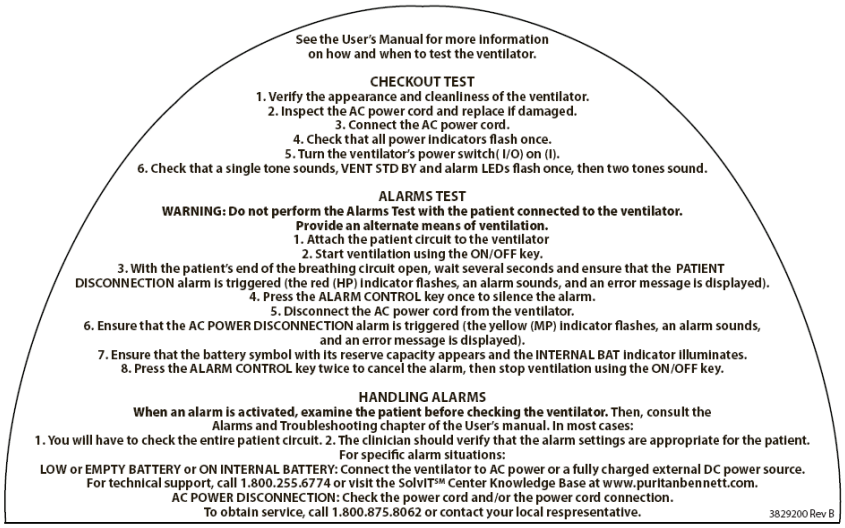
Table 1-1. Ventilator Symbols (Continued)

Symbols	Descriptions
	Year of Manufacture.
	Manufacturer.
	Audio Paused. This symbol means the sounding of audible alarms is currently disabled. For more information, refer to section 3.4, "Silencing the Audible Portion of Alarms".
	Alarm Paused (reset/cancelled). This symbol means one or more alarms have been paused, or reset/cancelled. For more information, refer to section 3.5, "Resetting/Pausing Alarms".
	Single patient use only (ISO 7000-1051). This symbol means that the labeled device is for use by a single patient only. Refer to Table 1-2, item 5.
	Freeze Waveforms. This symbol means the tracing of patient pressure and flow waveforms is currently paused or "frozen." For more information, refer to section 4.3, "Waveform Display".
	Follow instructions for use (ISO 7000-1641). This symbol directs the user to observe and adhere to the instructions contained in the product's user manuals.
	USB port. This symbol indicates a communications port for interfacing via a USB connector. See Figure 2-2, item 10. Not currently used.
	PC connector. This symbol indicates a port that can be used by authorized Puritan Bennett service personnel for software maintenance. See Figure 2-2, item 7.

1.5 Labels / Identification and Instruction Information

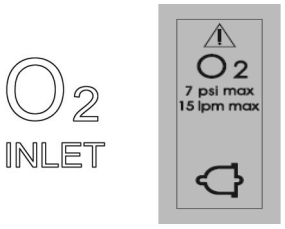
Various labels or specific markings are affixed to the ventilator that describe precautions to be taken for the correct use of the ventilator and contribute to the traceability of the product. Refer to Table 1-2 and the figures on the following pages for illustrations of these labels and markings and their locations on the ventilator. Use the item numbers in the following tables to locate the labels in Figure 1-1 through Figure 1-5.

Table 1-2. Ventilator Labels and Markings

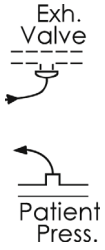

See the User's Manual for more information
on how and when to test the ventilator.
CHECKOUT TEST
1. Verify the appearance and cleanliness of the ventilator.
2. Inspect the AC power cord and replace if damaged.
3. Connect the AC power cord.
4. Check that all power indicators flash once.
5. Turn the ventilator's power switch(I/O) on (I).
6. Check that a single tone sounds, VENT STD BY and alarm LEDs flash once, then two tones sound.
ALARMS TEST
WARNING: Do not perform the Alarms Test with the patient connected to the ventilator.
Provide an alternate means of ventilation.
1. Attach the patient circuit to the ventilator
2. Start ventilation using the ON/OFF key.
3. With the patient's end of the breathing circuit open, wait several seconds and ensure that the PATIENT
DISCONNECTION alarm is triggered (the red (HP) indicator flashes, an alarm sounds, and an error message is displayed).
4. Press the ALARM CONTROL key once to silence the alarm.
5. Disconnect the AC power cord from the ventilator.
6. Ensure that the AC POWER DISCONNECTION alarm is triggered (the yellow (MP) indicator flashes, an alarm sounds,
and an error message is displayed).
7. Ensure that the battery symbol with its reserve capacity appears and the INTERNAL BAT indicator illuminates.
8. Press the ALARM CONTROL key twice to cancel the alarm, then stop ventilation using the ON/OFF key.
HANDLING ALARMS
When an alarm is activated, examine the patient before checking the ventilator. Then, consult the
Alarms and Troubleshooting chapter of the User's manual. In most cases:
1. You will have to check the entire patient circuit. 2. The clinician should verify that the alarm settings are appropriate for the patient.
For specific alarm situations:
LOW or EMPTY BATTERY or ON INTERNAL BATTERY: Connect the ventilator to AC power or a fully charged external DC power source.
For technical support, call 1.800.255.6774 or visit the SolvIT℠ Center Knowledge Base at www.puritanbennett.com.
AC POWER DISCONNECTION: Check the power cord and/or the power cord connection.
To obtain service, call 1.800.875.8062 or contact your local respresentative.
3829200 Rev B

1. Alarms Test Label (Figure 1-1, Figure 1-4)

2. Patient Gas Inlet Label (Figure 1-1, Figure 1-5)



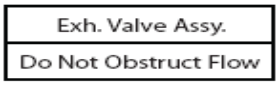
3. Oxygen Inlet Marking and Label (Figure 1-4)



4. Exhalation Valve and Patient Pressure Connection Label (Figure 1-1, Figure 1-3, Figure 1-5)

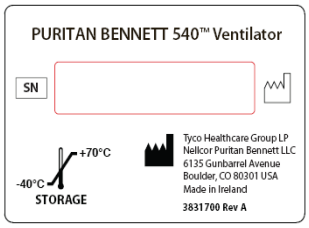
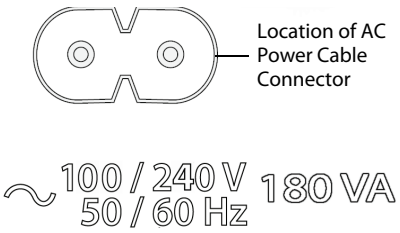
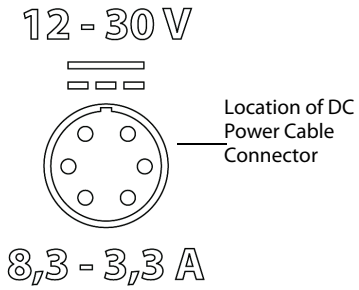
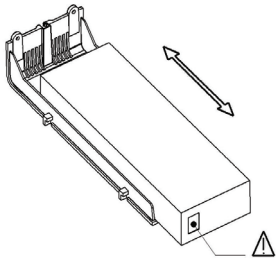
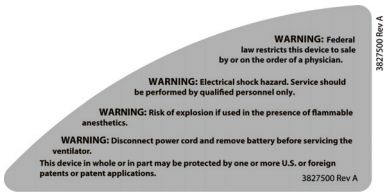
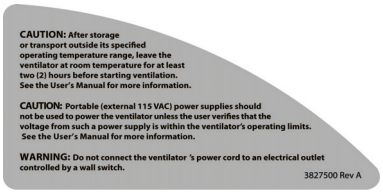
5. Exhalation Limb Connection of Patient Circuit – Single Use Exhalation Block Label (Figure 1-1, Figure 1-2, Figure 1-5)

6. Air Inlet Label (Figure 1-4)



7. Exhaled Gas Outlet Label (Figure 1-2, Figure 1-4)

Table 1-2. Ventilator Labels and Markings (Continued)

 **8.** Identification Label (Figure 1-5)	 **9.** AC Power (Mains) Cable Connector Marking (Figure 1-4)	 **10.** External DC Power Cable Connector Marking (Figure 1-4)
 **11.** Direction of Installation of Internal Battery Label (Figure 1-5)	 **12.** Warning - Caution Label (Figure 1-3)	 **13.** Warning - Caution Label (Figure 1-2, Figure 1-4)
14. See Instructions For Use Label (Figure 1-5)	**15.** PC Connection marking (Figure 1-4)	**16.** USB Port marking (Figure 1-4)
17. Nurse Call Cable Connector Marking (Figure 1-4)	**18.** ESD (Located inside the Device)	**19.** AC Mains Warning (Located Inside the Device)

Note: The item number callouts in the following figures refer to those listed in Table 1-2.

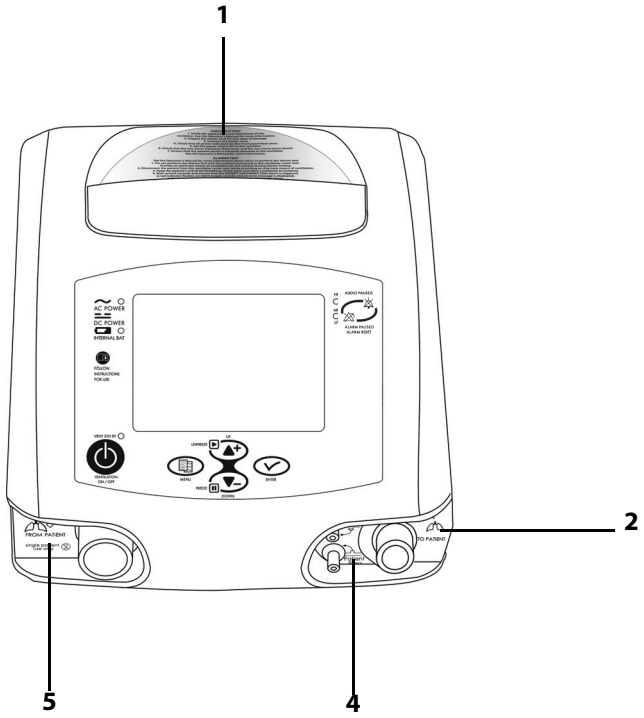


Figure 1-1. Locations of Labels – Top-Front View

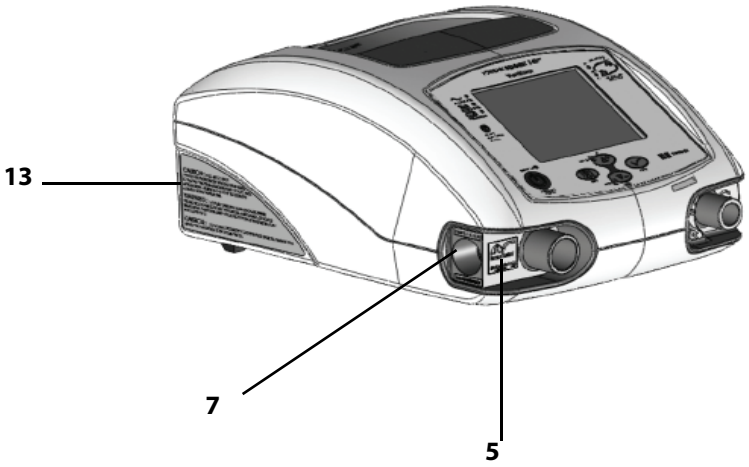


Figure 1-2. Locations of Labels – Front-Left View

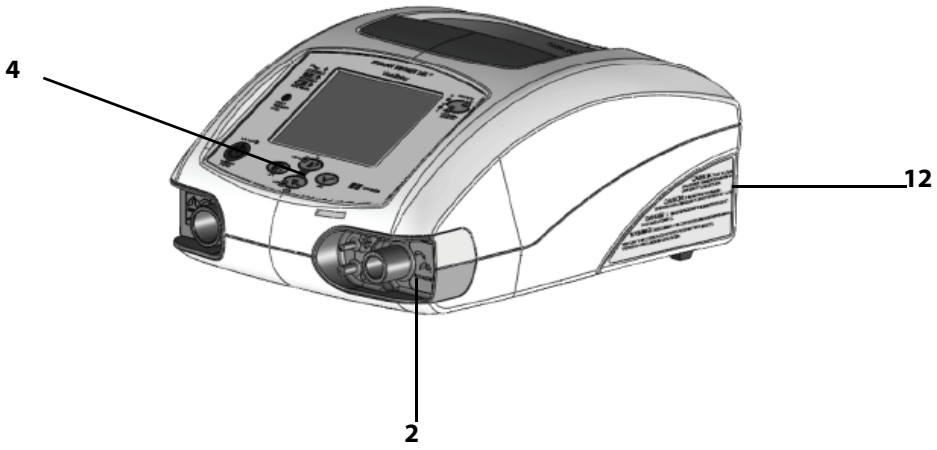


Figure 1-3. Location of Labels – Front-Right View

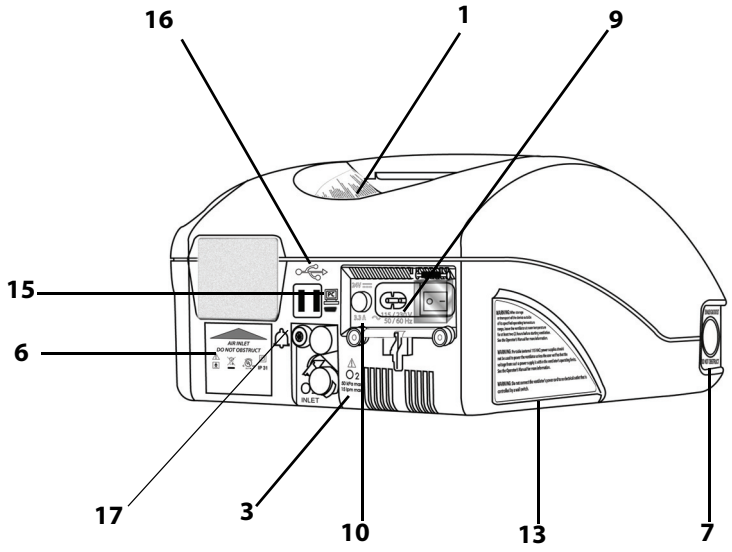


Figure 1-4. Location of Labels and Markings – Back-Left View

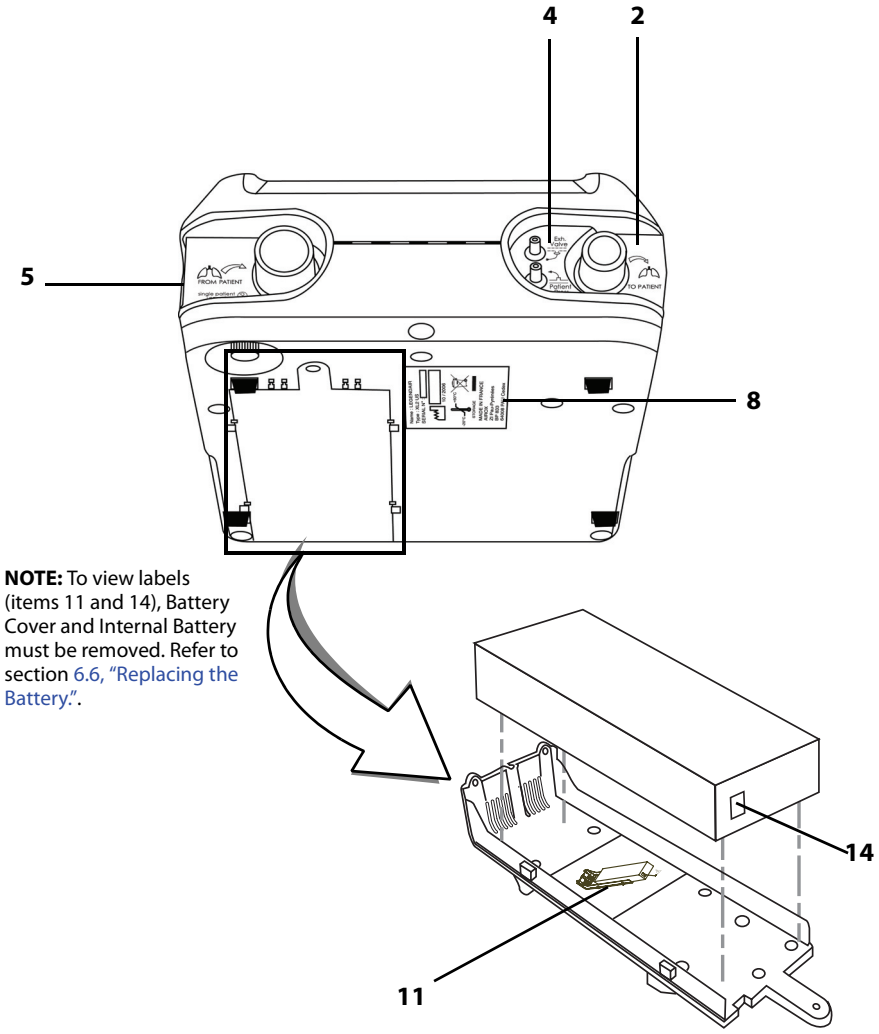

4
2
5
8
14
11
NOTE: To view labels (items 11 and 14), Battery Cover and Internal Battery must be removed. Refer to section 6.6, "Replacing the Battery.".

Figure 1-5. Location of Labels – Bottom-Front View

2 Ventilator Overview

2.1 Indications for Use

The Puritan Bennett 540™ Ventilator is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 11lb (5 kg) who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. It is essential to read, understand, and follow these instructions before using the Puritan Bennett 540™ Ventilator.

Target Patients

Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive Pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation
- Breath types including Volume Control, Pressure Control, and Pressure Support

Target Environments

The ventilator is suitable for use in institutional, home, and portable settings. It is not intended for use as an emergency transport ventilator.

Target Operators

The ventilator may be operated by:

- Respiratory therapists
- Physicians
- Nurses
- Home care providers
- Patient and patient's families

For more details on the knowledge and skill requirements for operating the Puritan Bennett 540™ Ventilator Ventilator, refer to Appendix A, "Patient/Caregiver Checklist" in the Clinician's Manual.

⚠ **WARNING**

Federal law restricts this device to sale by or on the order of a licensed physician.

2.2 Contraindications

This ventilator is not for use with anesthetic gases, and is not intended for use as an emergency transport ventilator.

2.3 Operational Use

The Puritan Bennett 540™ Ventilator uses a micro-turbine and the patient circuit with integral exhalation valve to provide ventilatory support to patients. Clinicians may use a variety of interfaces to connect patients to the ventilator: nasal or full face masks; endotracheal or tracheotomy tubes. User-selectable ventilation modes are:

- Assisted Controlled Volume (VOLUME A/C)
- Assisted Controlled Pressure (PRESSURE A/C)
- Synchronous Intermittent Mandatory Ventilation Volume (V SIMV)
- Synchronous Intermittent Mandatory Ventilation Pressure (P SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Pressure Support Ventilation (PSV)

Safety Net

Incorporated in the ventilator design is an alarm system that continuously monitors both patient and machine for signs of specific errors or faults that could lead to an unsafe condition. Should any of these errors or faults be detected, the alarm system announces the specific alarm condition both audibly and visually. The machine-related alarm conditions are factory set, whereas the patient-related alarm conditions are defined by alarm-threshold values selected by an operator (a clinician or a caregiver). For more information, refer to chapter 3, "Alarms and Troubleshooting."

Settings

A software key, known as the "Locking Key," restricts access to ventilation parameter settings and ventilation mode changes in order to distinguish between "clinician" usage and "patient" usage.

Oxygen Enrichment

Oxygen may be supplied from an external, low pressure source, but the oxygen flow must be limited to 15 lpm at 7.25 psi (50 kPa). The ventilator automatically compensates for the extra flow created by the external oxygen supply (refer to chapter 4, "Installation and Assembly.")

Breathing Circuit

The ventilator can be used with a single or double limb patient circuit. If exhaled volume monitoring is required (such as ventilator dependant patients), use the double-limb circuit for exhaled tidal volume or minutes volume monitoring. For more information, refer to section 4.4, "Patient Circuit," on page 4-6.

Note: It is highly recommended that users always possess an additional breathing circuit and valve while using the Puritan Bennett 540™ Ventilator.

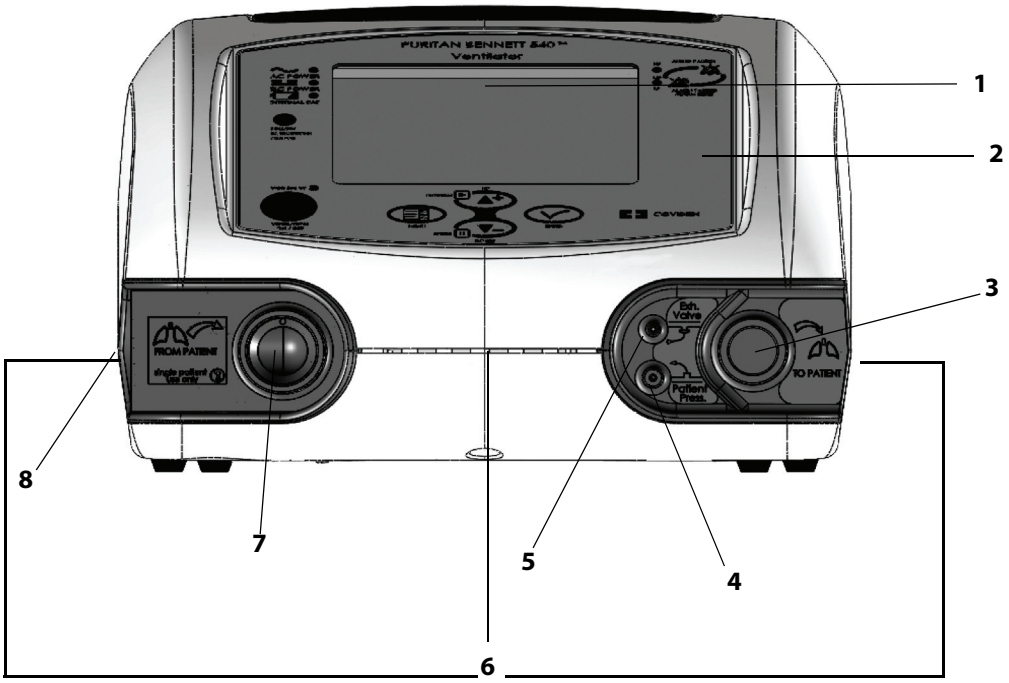
2.4 Device Classification

The ventilators IEC 60601-1classification is as follows:

- Protection/Insulation class (electric shock): Class II
- Protection index of enclosure: IP31
- Medical device directive classification: II B
- Degree of protection against risk of electric shock: BF
- Power: External (AC – mains, or DC – cigarette lighter) or internal (DC – battery)
- Operation mode: Continuous operation

For additional information, refer to section A, "Specifications."

2.5 Front Panel

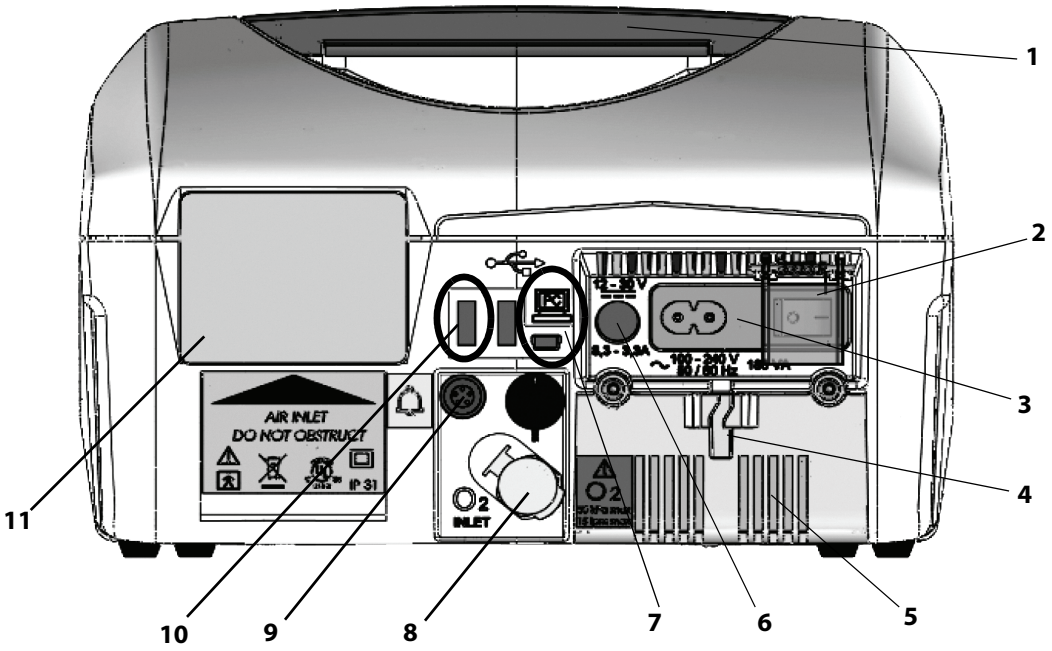


1	**LCD Display –** Displays information about the ventilator including patient hours and software version, ventilation modes and settings, and monitored and calculated patient data and waveforms. The display also allows the user to view and, using the Control Panel, adjust the ventilator's operating and alarm configuration settings.	5	**Exhalation Valve Port –** Nipple for providing piloting pressure to the exhalation valve. Controls the open-closed position of the exhalation valve.
2	**Control Panel –** Features the controls for setting up and operating the ventilator, and LEDs to indicate the ventilator's power source, ventilation On/Off status, and alarm priority level. Control functions include turning the ventilation on and off, configuring ventilation modes, silencing and canceling alarms, and setting device and alarm parameters.	6	**Lateral and Front Openings –** Vents that allow for air circulation to cool the ventilator's internal components. In addition, these openings function as sound ports for audible alarms. **⚠ WARNING** **Do not cover or obstruct these openings.**
3	**Patient Connection Port –** Provides an outlet for the air to be delivered to the patient via the patient circuit.	7	**From Patient Port -**Exhaled volume measurements are taken from this port, through which a portion of the exhaled gas is diverted to the exhalation flow sensor. VTE is calculated from this flow measurement.[a]
4	**Patient Pressure Monitoring Port –** Nipple for monitoring proximal patient pressure.	8	**Exhaled Gas Outlet–** Exhalation Valve connects here.

a. If exhaled volume monitoring is required, use the double-limb circuit for exhaled tidal volume or minutes volume monitoring.

Figure 2-1. Front Panel

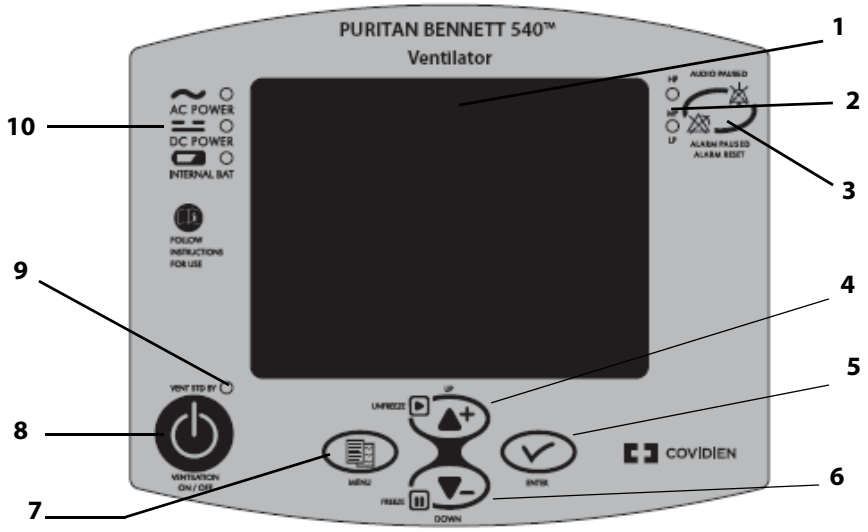
2.6 Back Panel



1	Ergonomic carrying handle.	**7**	PC Cable Connector: USB mini-B connector used for Puritan Bennett Ventilator Test Software.
2	On/Off (I/O) switch with protective cover: Device powered on in position I; device switched off in position 0.	**8**	O_2 Inlet Port: Connects the ventilator to a low pressure oxygen source via an adaptor connected to the O_2 Inlet (refer to section 4.8, "Oxygen," on page 4-13).
3	AC power ("Mains") cable connector.	**9**	Nurse Call Output Connector: Used to connect the ventilator to the nurse call system. Refer to section 4.10, "Mounting the Ventilator on the Utility Cart," on page 4-17.
4	AC power ("Mains") cable holding system: Prevents accidental disconnection of the AC power cable.	**10**	USB Key connection: USB functionality to allow for system upgrades. Not currently used.
5	Access cover for the internal battery.	**11**	Air Inlet Filter: Filters air as it enters the ventilator.
6	DC power cable connector with key.		

Figure 2-2. Back Panel

2.7 Control Panel

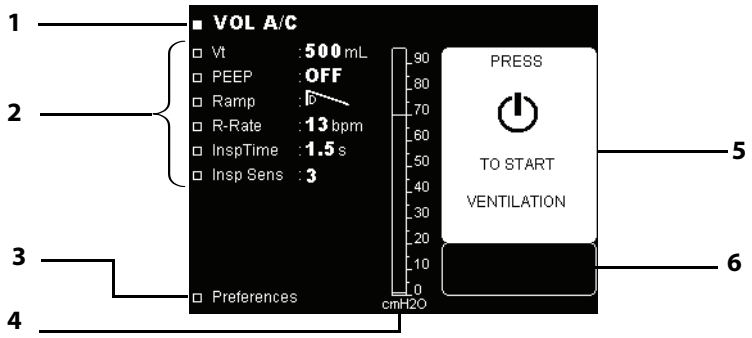


1	Display screen: Display of modes, ventilation settings, patient data and waveforms, configuration of the ventilator and alarm management.	**6**	DOWN/FREEZE key: • Moves the cursor down and decreases parameter values. • During ventilation, freezes displayed waveform in the Waveform menu.
2	Alarm indicators: Red indicator: • High priority (HP) alarm activated. Yellow indicator: • Medium priority (MP) alarm activated	**7**	MENU key: Changes the displayed menu. From the Ventilation menu screen, press this key to display the Alarm menu screen.
3	ALARM CONTROL key: • Press once to silence an audible alarm for 60 seconds. • Press twice to halt visual and audible alarms. If alarm is remedied, the alarm is cancelled (other than the high pressure alarm).	**8**	VENTILATION ON/OFF button: • Press briefly and release to start ventilation. • Press for three (3) seconds to stop ventilation.
4	UP/UNFREEZE Key: • Moves the cursor up and increases parameter values. • During ventilation reactivates waveform tracing in the Waveform menu.	**9**	Ventilation status indicator: • Blue indicator illuminated: device is powered on and ventilation is off (on standby). • Blue indicator off: ventilation is on.
5	ENTER key: • Access to a setting value and validation of the modification of this setting. • Access to a sub-menu.	**10**	Electrical power source indicators: • AC POWER indicator lit: AC power source connected. • DC POWER indicator lit: DC power source connected. • INTERNAL BAT indicator lit continuously: Ventilator powered by internal battery (no external power source connected.) • INTERNAL BAT indicator flashing: battery charging.

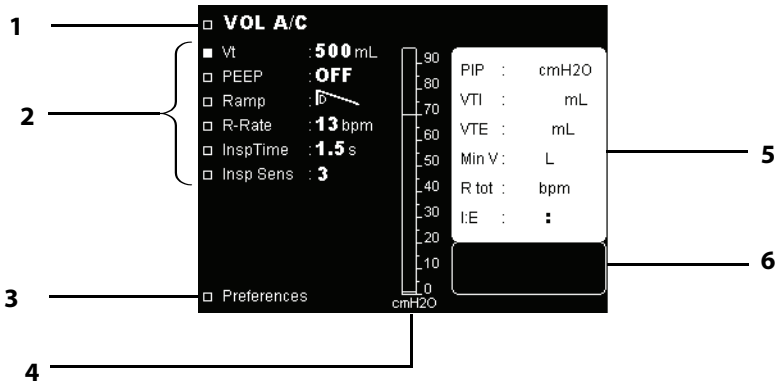
Figure 2-3. Control Panel

2.8 Ventilation Menu

Ventilation menu with ventilation on standby.



Ventilation menu during ventilation.

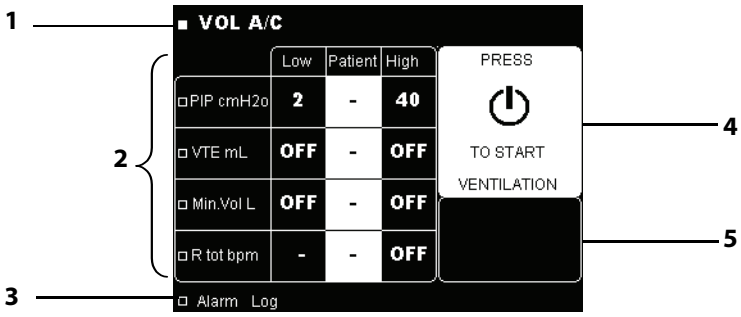


1	General information line: Displays the current ventilation mode, along with the following: • Battery symbol if the device is powered by the internal battery. • Audio paused symbol if an alarm is currently inhibited. • Alarm paused symbol if an alarm has been canceled manually and the cause of the alarm remains.	**2**	Ventilation settings: Displays the specific ventilation parameter values for the currently selected ventilation mode. Refer to chapter 3, "Operating Parameters" for more information.	**3**	Preference menu access line: Highlight this line and press the ENTER key to display the Preference menu.
4	Bargraph: Displays pressure generation during ventilation.	**5**	Status/monitored data window: • Ventilation stopped (Standby): displays the message, "PRESS TO START VENTILATION." • Ventilation on: parameters are monitored and displayed. • The Inspiratory Effort Detected symbol appears adjacent to the monitored I:E ratio when the patient actively triggers a breath.	**6**	Alarm conditions window: • For Active alarms, scrolls through active alarm messages in flashing reverse video. • For Inactive alarms, displays the last alarm along with its trigger date and end-of-event time. Refer to chapter 3, "Alarms and Troubleshooting" for details.

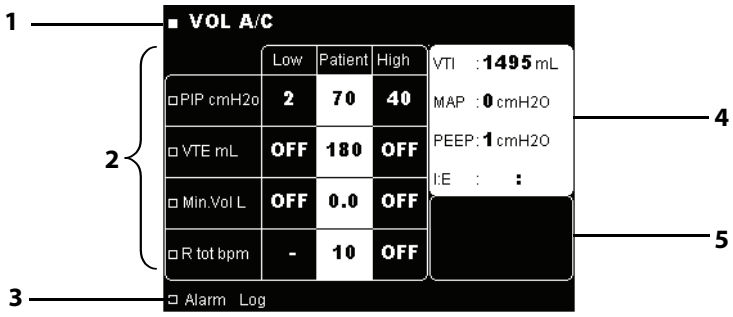
Figure 2-4. Ventilation Menu Display

2.9 Alarm Menu

Alarm menu with ventilation on standby.



Alarm menu when not in standby.

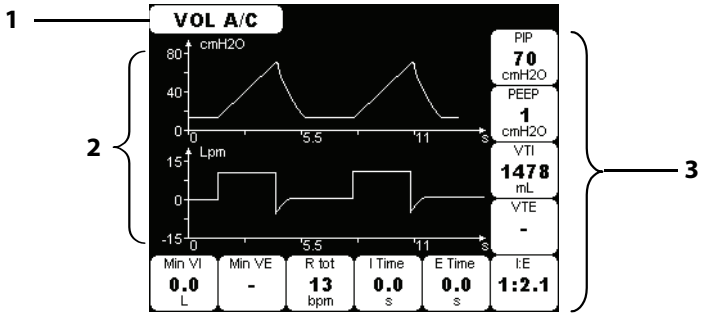


1 Title line: Displays ventilation mode and the following symbols: • Battery if the ventilator is powered by the internal battery. • Audio paused if an alarm is currently inhibited. • Alarm paused if an alarm has been canceled manually and the cause of the alarm remains.	**2** Alarm settings: Displays the specific alarm parameter values for the currently selected ventilation mode, which are: • Low and High alarm threshold settings, and • Current monitored patient readings, or hyphen (-) when ventilation is in standby.	**3** Access line to Alarm Log menu. Highlight this line and press the ENTER key to display the Alarm Log menu. Refer to manual section 3.3, "Alarm Logs Menu," on page 3-3.
4 Status/monitored data window: • Ventilation stopped (Standby): displays the message, "PRESS TO START VENTILATION." • Ventilation on: parameters are monitored and displayed. • The Inspiratory Effort Detected symbol appears adjacent to the monitored I:E ratio when the patient actively triggers a breath.	**5** Alarm message window: • For Active alarms, scrolls through active alarm messages in flashing reverse video. • For Inactive alarms, displays the last alarm along with its trigger date and end-of-event time. Refer to chapter 3, "Alarms and Troubleshooting" for more information.	

Figure 2-5. Alarm Menu

2.10 Waveforms Menu

The display of waveforms (Figure 2-6) is optional and can be selected in the using the Menu key (refer to chapter 4, "Monitored Parameters."). The Waveform menu is only accessible when ventilation is active.



1	Title line: Displays ventilation mode and the following symbols: • Battery if the ventilator is powered by the internal battery. • Audio paused if an alarm is currently inhibited. • Alarm paused if an alarm has been canceled manually and the cause of the alarm remains. • Freeze Waveforms if the tracing of patient waveforms has been halted during ventilation.	**2**	Graphic zone: Displays the patient's pressure and flow waveforms as a function of time.	**3**	Numeric zone: Displays monitored data.

Figure 2-6. Waveforms Menu

2.11 If Ventilator Failure Occurs

If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternate means of ventilation.

Keep in mind that troubleshooting information is available in this manual to assist you in the event of a problem. Refer to chapter 3, "Alarms and Troubleshooting".

If you cannot determine the cause of a problem, contact your equipment supplier or Puritan Bennett.

Puritan Bennett Technical Services (USA):

1-800-255-6774

3 Alarms and Troubleshooting

WARNING
Setting Alarm limits to extreme values can cause the ventilator alarms to malfunction.

The alarms or faults generated by your Puritan Bennett 540™ Ventilator are classified into two categories:

- Ventilation (or utilization) alarms
- Technical faults

Some of the ventilator alarms are adjustable, depending on ventilation modes (refer to chapter 3, "Operating Parameters"). Automatic, unadjustable alarms also exist to create a safety net for safe patient ventilation.

Alarms indicate events likely to affect the ventilation in the short term and necessitate rapid intervention (refer to section 3.8, "Troubleshooting," on page 3-14).

Technical faults do not directly affect machine operation. Therefore, the user is not alerted to technical faults. Only authorized and trained technicians may consult the maintenance menu (refer to the Puritan Bennett 540™ Service Manual).

Note:

Default alarm setting preferences should be entered prior to using the ventilator.

3.1 Alarm Level of Priority

The alarm hierarchy for signaling the level of alarm criticality is listed below.

- **Very High Priority (VHP): Immediate critical situation; ventilation is impossible:**

  Continuous Sound Signaling / With or Without Continuous Red LED Illumination / With or Without Message / With or Without Display Lighting (it is possible for an alarm condition to occur that may not have **both** a message and lighting).

- **High Priority (HP): Critical situation in the short term; ventilation is potentially compromised:**

  High Frequency Sound Signaling / Flashing Red LED Illumination / With Message / With Display Lighting

- **Medium Priority (MP): Critical situation in the long term; ventilation is not affected in the short term:**

  Medium Frequency Sound Signaling / Flashing Yellow LED Illumination / With Message / With Display Lighting

Note:

There are currently no Low Priority (LP) Alarms.

Note:

If there is no corrective action and if the audible alarm is not inhibited (Audio Paused) or reset (Alarm Reset) within 60 seconds, High Priority alarms will sound at the maximum level of 85 dB(A).

3.2 Alarm Display

During operation, when an alarm is activated:

- One of the red or yellow alarm indicators to the left of the **ALARM CONTROL** key illuminates and flashes.
- An alarm tone sounds.
- A message is displayed and flashes in reverse video at the bottom of the Ventilation Menu or Alarm Menu.

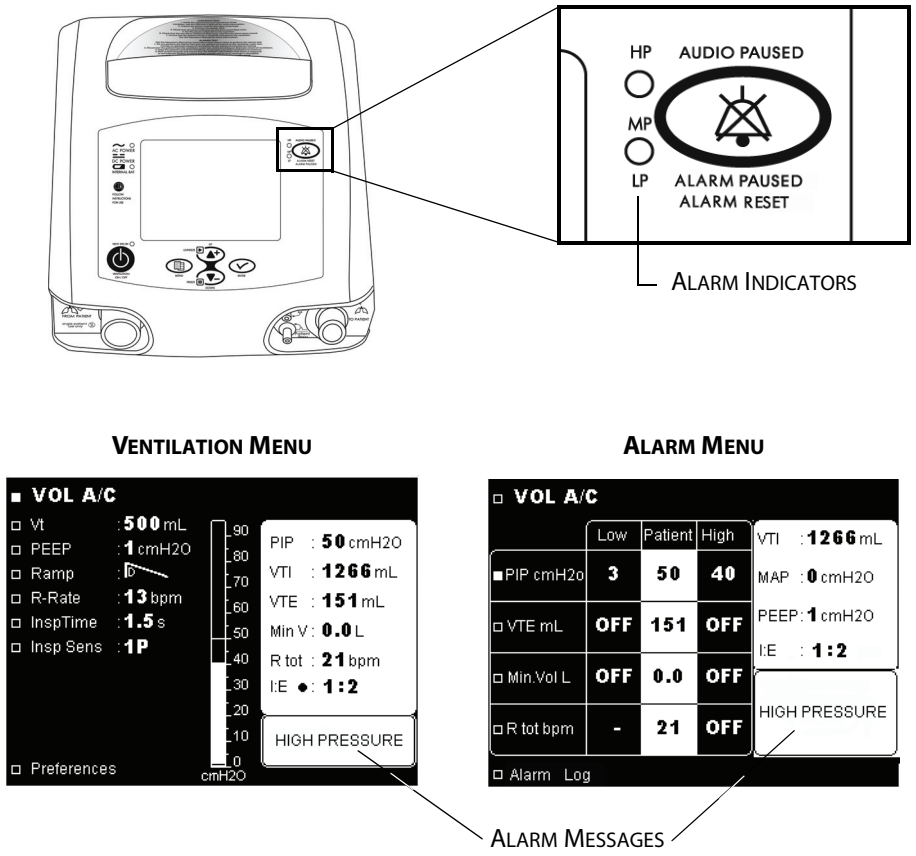


Figure 3-1. Alarm Displays

Note:

There are currently no Low Priority (LP) Alarms.

When an alarm is triggered, if the current menu displayed is not the Ventilation parameters or Alarm menu, the display automatically switches to one of these menus to display the alarm message.

In the event several alarms are activated at the same time, the highest priority audible and visual alarm is highlighted; however, all active messages are displayed, in the sequence in which they occurred.

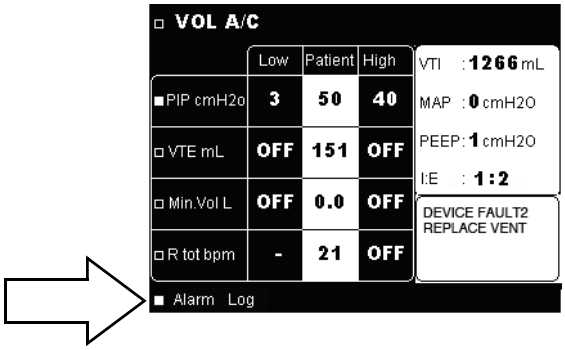
3.3 Alarm Logs Menu

All alarms are recorded in the internal memory of the ventilator at the time they are activated.

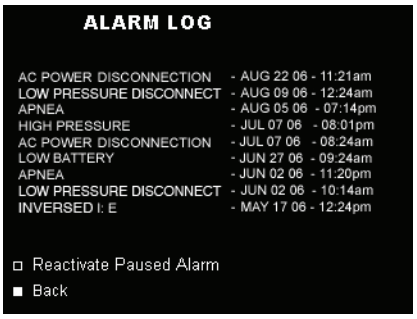
The Alarm Logs menu is used to display the last eight (8) alarms activated, along with their date and time of activation.

To access the Alarm Logs menu, do the following:

1. Press the **MENU** key to access the alarm setting menu (if this is not the menu currently displayed).
2. Press the **DOWN** key several times or press until the cursor is on the "Alarm Logs" line at the bottom of the page. The display appears as follows:

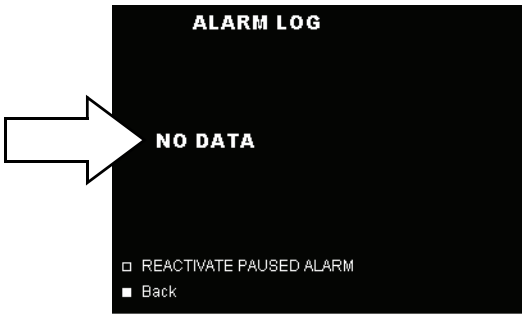


3. Press the **ENTER** key. The Alarm Logs screen is displayed.


ALARM LOG
AC POWER DISCONNECTION - AUG 22 06 - 11:21am
LOW PRESSURE DISCONNECT - AUG 09 06 - 12:24am
APNEA - AUG 05 06 - 07:14pm
HIGH PRESSURE - JUL 07 06 - 08:01pm
AC POWER DISCONNECTION - JUL 07 06 - 08:24am
LOW BATTERY - JUN 27 06 - 09:24am
APNEA - JUN 02 06 - 11:20pm
LOW PRESSURE DISCONNECT - JUN 02 06 - 10:14am
INVERSED I: E - MAY 17 06 - 12:24pm
Reactivate Paused Alarm
Back

Note:

When no alarm has been activated, "NO DATA" is displayed on the screen (see graphic below).



For more information on the "Reactivate Paused Alarm" line, refer to section 3.6, "Re-activating Alarms," on page 3-6.

To dismiss the Alarm Logs screen manually:

Press the **ENTER** key when the cursor is on the "Back" line.

The Alarm Logs screen is dismissed automatically:

- After 15 seconds if no keyboard action is detected
- When a High Priority alarm is triggered

Note:

Only qualified service personnel may access all alarms and events recorded by the ventilator. Qualified personnel should refer to the Puritan Bennett 540™ Service Manual for further information.

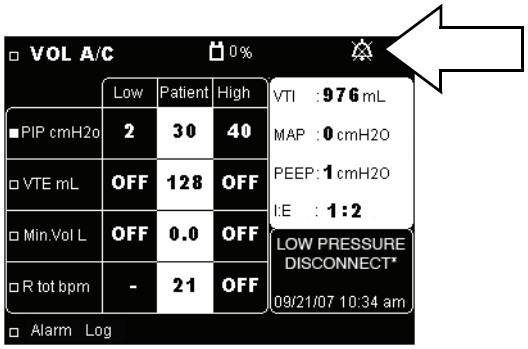
3.4 Silencing the Audible Portion of Alarms

You may silence the audible portion of alarms for 60 seconds at a time. This is referred to as the Audio Paused function.

To silence the audible portion of activated alarms:

Press the **ALARM CONTROL** key.

- The audible portion of all activated alarms is paused.
- The visual portions (light indicator and message) of activated alarms remain visible.
- The Audio Paused symbol is displayed at the top right of the screen while the audio pause function is active.



If several alarms are activated at the same time, pressing the **ALARM CONTROL** key affects all current alarms.

The audible portion of activated alarms is automatically reactivated:

- After 60 seconds, if the cause(s) of the alarm(s) persist(s)
- Whenever a new alarm is activated

Note:

If a key is stuck or held down for 45 seconds a keypad alarm will occur.

3.5 Resetting/Pausing Alarms

WARNING

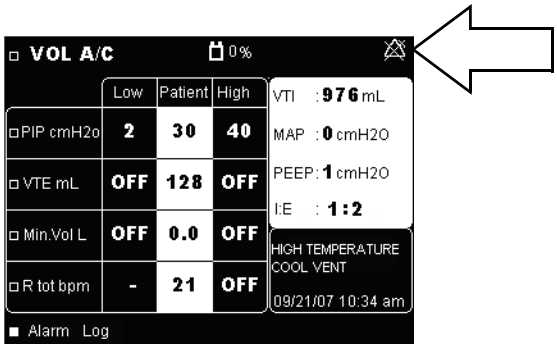
- **Alarm volume should be adjusted with respect to the ventilator's operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused with the Alarm Pause function by pressing the ALARM CONTROL key twice once the alarm has been declared.**
- **When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.**

Some alarms are not automatically cancelled when the condition causing the alarm ceases; these can be paused manually even if the cause(s) of their activation remain(s).

To manually pause an alarm, proceed as follows:

Press the **ALARM CONTROL** key twice.

- The alarm is paused: the audible portion, light indicator, and message are all halted (for the alarms which can be paused manually).
- The Alarm Paused symbol is displayed at the top right of the Ventilation, Alarms, and Waveforms screens. See the sample screen, below.



When no other alarms are currently activated, the last alarm cancelled is displayed continuously in the alarm message window in the Alarms menu, along with the date and time of its activation (as shown above).

The High Pressure alarm must be manually reset. Refer to section 3.7, "Overview of Alarms," on page 3-7.

To manually reset the High Pressure Alarm, proceed as follows:

Press the **ALARM CONTROL** key twice.

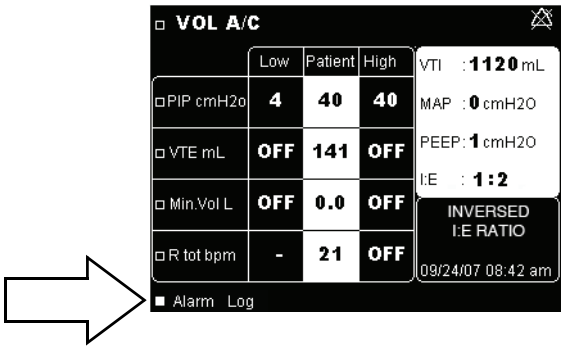
- The visual alarms will be reset.

3.6 Re-activating Alarms

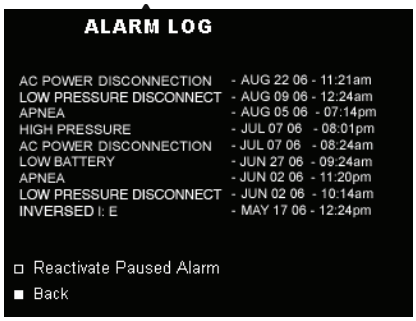
Alarms that have been paused and whose activation conditions continue to exist can be reactivated.

To reactivate alarms, proceed as follows:

1. Press the **MENU** key to access the Alarm Setting menu, if this is not the menu currently displayed.
2. Press the **DOWN** key to position the cursor on the "Alarm Logs" line, if this is not already the case. The following graphic shows an example of the resulting display.



3. Press the **ENTER** key, to confirm access to the "Alarm Logs" menu.
4. Press the **UP** key to position the cursor on the "Reactivate Paused Alarm" line. The following graphic shows the resulting display.


ALARM LOG
AC POWER DISCONNECTION - AUG 22 06 - 11:21am
LOW PRESSURE DISCONNECT - AUG 09 06 - 12:24am
APNEA - AUG 05 06 - 07:14pm
HIGH PRESSURE - JUL 07 06 - 08:01pm
AC POWER DISCONNECTION - JUL 07 06 - 08:24am
LOW BATTERY - JUN 27 06 - 09:24am
APNEA - JUN 02 06 - 11:20pm
LOW PRESSURE DISCONNECT - JUN 02 06 - 10:14am
INVERSED I: E - MAY 17 06 - 12:24pm
Reactivate Paused Alarm
Back

5. Press the **ENTER** key for at least three (3) seconds. The following events occur:
   - A "beep" sounds.
   - An audible alarm sounds.
   - An alarm indicator illuminates.
   - The messages of all active alarms are displayed in a loop in the Ventilation and Alarm menus.
   - The Audio Paused symbol disappears (if it was displayed).
   - The Alarm Paused symbol disappears.

3.7 Overview of Alarms

Note:

The message: "*IF PERSISTS REPLACE VENT" will occur only if the alarm condition continues for longer than 30 seconds.

Table 3-1. Overview of Alarms

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
AC POWER DISCONNECTION	Cut-off of the AC (mains) power supply. Alarm activation occurs: • After 5 seconds if ventilation is stopped • At the start of a ventilation cycle when ventilation is in progress. Consequence: switch over to external DC power supply if present, otherwise to the internal battery.	MP	Yes	Yes
APNEA	No inspiratory trigger detected by the ventilator after the apnea time set in PSV/CPAP, P SIMV and V SIMV modes. Automatically clears itself after two successive patient breaths.	MP	Yes	Yes – except for CPAP
BATT FAULT1 CALL SERVICE	Ventilator has detected an internal battery fault. Consequence: the internal battery is disabled from use.	MP	Yes	No
BATT FAULT2 CALL SERVICE	No internal battery detected.	MP	Yes	No
BATT FAULT3 CALL SERVICE	The internal battery is not recognized as a Puritan Bennett battery.	MP	Yes	No
BATT FAULT4 REPLACE VENT	Internal battery charging failure. Consequence: charging of the internal battery impossible.	MP	Yes	Yes
BATT TEMP FAULT* *IF PERSISTS REPLACE VENT	Battery temperature out of tolerance. Consequence: battery charging stops.	MP	Yes	Yes
CAL FAULT SEE USER MNL	Failure of one calibration point of the internal exhaled flow sensor. Consequence: failed calibration point is replaced by the default point.	MP	Yes	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
CHECK PROXIMAL LINE1 *IF PERSISTS REPLACE VENT	1. Loss of signal from the proximal pressure sensor Consequence: switch to internal pressure sensor for the pressure measurement. Alarm activation occurs: • In the event of signal loss (1): After one ventilation cycle or In the event of signal loss(2) and after the 17th breath cycle: After 17 seconds for PRES A/C and VOL A/C modes, or after the maximum time between 17 seconds and Apnea Time + 4 seconds for CPAP/PSV/ P SIMV, and V SIMV modes	MP	Yes	No
CHECK PROXIMAL LINE2 *IF PERSISTS REPLACE VENT	Proximal pressure < 0.6 cmH2O for 100 ms during inspiration phase of 2nd breath cycle Ventilator response: Switch to internal pressure sensor for pressure measurement.	MP	Yes	No
CHECK/CHANGE EXH VALVE2	Abnormally high expired flow during the inspiratory phase of three consecutive breaths (in double-limb setup). Alarm activation occurs: After three consecutive breaths.	MP	Yes	No
CHECK SETTINGS	Alarm activation occurs: • Systematically after software versions have changed. • Loss of memorized parameters Consequence: • Locking Key disabled • Out-of-range settings are replaced by their default values	MP	Yes	Yes
CHK EXH VALV RESTART VENT* *IF PERSISTS REPLACE VENT	• Faulty pressure valve sensor signal at ventilation start.	HP	Yes	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
CHECK/CHANGE EXH VALVE1* *IF PERSISTS REPLACE VENT	Inspired tidal volume during exhalation < 40% of Inspired Tidal volume and inspired tidal volume inspired tidal volume > 20mL	HP	Yes	No
CHK VOL/INSP TIME SETTINGS* *IF PERSISTS REPLACE VENT	Measurement and calculation of tidal volume do not match Vt set during six consecutive breaths in VOL inspired and V SIMV modes. Alarm activation occurs: • After six consecutive breaths—once the ventilator has reached its performance limits.	HP	Yes	No
DEVICE FAULT1 REPLACE VENT	Faulty internal pressure sensor signal. Alarm activation occurs: • After 15 seconds.	HP	Yes	No
DEVICE FAULT2 REPLACE VENT	Faulty proximal pressure sensor signal. Alarm activation occurs: • After 15 seconds.	MP	Yes	Yes
DEVICE FAULT3 REPLACE VENT	Failure in the 24 V power supply.	HP	Yes	No
DEVICE FAULT4 REPLACE VENT	Ventilator cooling fan operating speed not suited to the internal ambient temperature of the device.	MP	Yes	Yes
DEVICE FAULT5 REPLACE VENT	Detection of a fault in the electrical power supply system. Consequence: the internal battery capacity is not displayed beside the battery symbol.	MP	Yes	Yes
DEVICE FAULT6 REPLACE VENT	Turbine speed too high with high temperature. Consequence: ventilation stops immediately and O2 supply stops.	HP	No	No
DEVICE FAULT7 REPLACE VENT	Detection of a fault in sensor voltage measurement.	HP	Yes	No
DEVICE FAULT8 REPLACE VENT	Inspiratory flow is constant (+/- 1 lpm) with normal turbine temperature and speed conditions. Contact your service representative for assistance.	HP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
DEVICE FAULT9 REPLACE VENT	POST RAM Error. RAM Read/Write does not match memory setting.	VHP	No	No
DEVICE FAULT10 REPLACE VENT	POST FLASH Checksum Error. Startup FLASH computed checksum does not match memory setting.	VHP	No	No
DEVICE FAULT11 REPLACE VENT	POST EEPROM Error. Startup EEPROM does not match memory setting.	VHP	No	No
DEVICE FAULT12 REPLACE VENT	POST Reference Voltage Error. 5V or 10V reference voltage error.	VHP	No	No
DEVICE FAULT13	Software Version Error.	VHP	No	No
EMPTY BATTERY	Internal battery capacity < 10 min. or 2%. (battery voltage < 22.5V) Consequence: ventilation comes to a halt.	HP	No	No
EXHSENS FAULT OR CRKT LEAK	At least four of the last six spontaneous breaths are terminated by time.	MP	Yes	No
HIGH DEVICE TEMP COOL VENT* *IF PERSISTS REPLACE VENT	Device internal ambient temperature out of tolerance range.	MP	Yes	Yes
HIGH EXH VOLUME	Expired tidal volume greater than High VTE set during three consecutive breaths (in double limb setup). Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
HIGH INSP VOLUME	Inspired tidal volume greater than High VTI set during three consecutive breaths in PSV/CPAP, PRES A/C, P SIMV, and V SIMV modes. Alarm activation occurs: • After three consecutive breaths.	HP	Yes	No
HIGH MINUTE VOLUME	Minute volume higher than High MinVol set during three consecutive breaths. Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
HIGH PRESSURE	• In VOL A/C or V SIMV modes, if Inspiratory Pressure is higher than High PIP during three consecutive cycles. or • In PSV/CPAP, PRES A/C, or P SIMV modes, if Inspiratory Pressure is higher than (P Support or P Control + PEEP) + 5 cmH_2O up to 29 cmH_2O or + 10 cmH_2O over 30 cmH_2O during three consecutive cycles. or • In PSV/CPAP mode and P Support is set to off, if Inspiratory Pressure is higher than PEEP + 10cmH2O during three consecutive cycles. Alarm activation occurs: • After three consecutive breaths. Consequence: • Switch to exhalation phase.	HP Note: When alarm condition becomes false, alarm priority indicator must be manually reset by pressing the key.	Yes	No
HIGH RATE	Rate measured greater than High Rtot set during three consecutive breaths. Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
INVERSED I:E RATIO	An Insp Time setting that results in an inspiratory time greater than the exhalation time. Alarm activation occurs: • Upon setting parameter values, such that the Insp Time value exceeds the limit described above.	MP	Yes	Yes
KEYPAD FAULT CALL SERVICE* *IF PERSISTS REPLACE VENT	Keyboard key held down for more than 45 seconds.	HP	No	No
LOW BATTERY	Internal battery capacity < 30 min. or 5%.	HP	Yes	No
LOW EXH VOLUME	Expired tidal volume less than Low VTE set during three consecutive breaths (in double-limb setup). Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
LOW INSP VOLUME	Inspired tidal volume less than Low VTI set during three consecutive breaths in PSV/CPAP, PRES A/C, P SIMV and V SIMV modes. Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
LOW MINUTE VOLUME	Minute volume lower than Low Min Vol set during three consecutive breaths. Alarm activation occurs: • After three consecutive breaths	MP	Yes	No
LOW PRESSURE DISCONNECT* *IF PERSISTS REPLACE VENT	• If the flow is greater than 130 lpm during the inspiratory phase. or • In VOL A/C and V SIMV modes, if patient pressure is lower than Low PIP. or • In PSV/CPAP, PRES A/C modes and P SIMV if patient pressure is lower than (P Support + PEEP) - 20% or (P Control + PEEP) - 20%. Alarm activation occurs: If one of these three conditions remains for more than 15 seconds, or the maximum time between 15 seconds and Apnea Time + 2 seconds.	HP	Yes	No
LOW SPKR/BATTERY	Occurs when the buzzer battery is too low to sound an alarm when ventilating using battery power. Connecting the ventilator to AC power for 15 minutes should clear the alarm.	MP	Yes	Yes
OCCLUSION CHECK CIRCUIT* *IF PERSISTS REPLACE VENT	Tidal volume measured negligible during three consecutive breaths for PSV/CPAP, PRES A/C and P SIMV modes. Alarm activation occurs: • After three consecutive breaths.	HP	Yes	No
ON INTERNAL BATTERY (with Periodic Audible Signal)	Cut-off of the external DC power supply. Consequence: switch-over to the internal battery.	MP	Yes	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
POWER FAULT REPLACE VENT	Detection of a fault in the electrical power supply system.	MP	Yes	Yes
POWER SUPPLY LOSS (no message)	1. Electrical power supply to the machine is interrupted with the I/O switch when ventilation is in progress or 2. Battery fully discharged when it was the only source of power to the ventilator. Consequence: ventilation stops immediately. Ventilation restarts immediately when the switch is pressed in case 1 (above) or after restoration of the AC or DC supply in case 2 (above).	VHP	No	Yes
REMOTE ALARM FAULT	No activation of Nurse Call when an alarm is in progress.	MP	Yes	Yes
SOFTWARE VERSION ERROR	Detection of a wrong software version.	NA	NA	NA
SPKR FAULT1 REPLACE VENT	Defective operation of the buzzers. Consequence: no audible tone when an alarm is activated.	MP	Yes	No
SPKR FAULT2 REPLACE VENT	Failure detected in the Very High Priority buzzer. Consequence: no audible alarm in case of involuntary stop of the ventilation.	MP	Yes	Yes
SPKR FAULT3 REPLACE VENT	Battery Charge Failure due to incorrect voltage. Contact your service representative for assistance.	HP	Yes	No
SPKR FAULT4 REPLACE VENT	Buzzer Battery Failure. The Battery Buzzer Voltage is too low, disabling the buzzer. Contact your service representative for assistance.	MP	Yes	Yes

3.8 Troubleshooting

Caution

- This manual tells you how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.
- To ensure proper servicing of the ventilator and reduce the possibility of physical injury, only qualified personnel should attempt to service the Puritan Bennett 540™ Ventilator.

3.8.1 Alarms

⚠ **WARNING**

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

Table 3-2 offers a guide to the most likely ventilator alarms, possible reasons for the alarms, and corrective actions.

WARNING

Except for replacing the internal battery and cleaning the device, do not try to repair or otherwise service the ventilator yourself, or modify the ventilator, its components, or accessories. Doing so might endanger the patient, cause damage to the ventilator, and/or void your warranty. Only qualified service personnel should attempt repair of the ventilator.

Table 3-2. Alarms and Corrective Actions

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
AC POWER DISCONNECTION	AC (“mains”) power source cut off.	Cancel the alarm then check the supply cable and/or the effective availability of a voltage on the AC power (“mains”) port.
	Starting with 12 – 30 VDC external power supply.	Cancel the alarm.
	Current-limiting fuse of the device blown.	Replace the ventilator and call for the maintenance technician.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
AMBIENT TEMP. ALERT	Internal ambient temperature of the device out of the tolerance ranges.	**CAUTION:** Ensure that you are operating the ventilator within the proper temperature range (refer to Appendix A, "Specifications"). Put the device in a warmer environment (if the ambient temperature is too low) or in a cooler environment (if the ambient temperature is too high). **⚠ WARNING** **In case of operation in a high ambient temperature, handle the ventilator with care; some portions of the device may have high surface temperatures.** **⚠ WARNING** **In the case of high ambient temperatures, it may take a significant period of time to cool the internal temperature of the ventilator to the proper operating range. To avoid injury to the patient, ensure that the air inspired by the patient does not exceed 106 °F (41 °C). If in doubt, replace the ventilator.**
AMBIENT TEMP. ALERT	Defective internal temperature probe or any other technical anomaly.	Replace the ventilator and call your customer service representative.
APNEA	Patient's breathing effort less than the Sensitivity control setting.	Under the guidance of a Clinician adjust the Insp Sens setting that which is appropriate for the patient.
	Patient apnea.	Examine the patient for breathing effort and stimulate if necessary.
	Defective sensors.	Have a qualified technician replace the defective component(s) and call your customer service representative.
BATT FAULT1 CALL SERVICE	Battery problem that prevents it from operating.	Replace the ventilator and call your customer service representative.
BATT FAULT2 CALL SERVICE	Internal battery missing or not detected.	Replace the ventilator and call your customer service representative.
BATT FAULT3 CALL SERVICE	Internal battery not recognized as a Puritan Bennett battery.	Call your customer service representative.
BATT FAULT4 REPLACE VENT	Battery charging impossible.	Do not disconnect the ventilator from the AC power supply. Ensure that the power cable is installed according to the instructions in chapter 4, "Installation and Assembly", so that the power cable cannot be involuntarily disconnected. In the event the internal battery capacity is low, use an alternate device to ventilate the patient. Call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
BATTERY TEMPERATURE FAULT	Battery temperature out of the tolerance ranges. Defective internal temperature probe or any other technical anomaly inside the battery.	**CAUTION:** Ensure that ventilator is being used according to the operating instructions found in Appendix A, "Specifications". If the ambient temperature is too low, place the device in a warmer environment. If the ambient temperature is too high, place the ventilator in a cooler environment. ⚠ **WARNING** **In case of operation in a high ambient temperature, handle the ventilator with care; some portions of the device may have high surface temperatures.** Call your customer service representative. **CAUTION:** Do not attempt to charge a defective battery; such a battery cannot be charged.
CALIBRATION FAULT	Too large a difference between a calibration point and its tolerance range.	Restart calibration.
	Defective expiratory flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
CHECK EXH. VALVE RESTART VENT* *IF PERSISTS REPLACE VENT	Obstruction or abnormal damage of the exhalation valve.	Clean or replace the exhalation valve and/or its control tube.
	Defective connection or defective exhalation valve tubing.	Reconnect the valve or replace the exhalation valve and/or the exhalation valve pilot pressure tube.
	Defective inspiratory flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
CHECK PROXIMAL LINE1* *IF PERSISTS REPLACE VENT	No connection of the proximal pressure tube when ventilation starts.	Reconnect the proximal pressure line.
	Proximal pressure line disconnected or obstructed.	Reconnect the connection line or replace it if obstructed.
	Defective proximal pressure sensor or internal leak of the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative..
CHECK SETTINGS	Loss of memorized parameters.	Check and adjust the prescribed parameters, if necessary.
	Software versions have changed.	
CHECK/CHANGE EXH VALVE1 * *IF PERSISTS REPLACE VENT	Large leakage detected on the patient circuit return limb during the inspiratory phase.	Replace the exhalation valve and/or its control tube.
	Contaminated or defective expiratory flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
CHK VOL/INSP TIMESETTINGS *IF PERSISTS REPLACE VENT	Defective inspiratory flow sensor or internal leak of the machine.	Replace the defective device(s) and have a qualified technician check them.
DEVICE FAULT1 REPLACE VENT	Defective internal pressure sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
DEVICE FAULT2 REPLACE VENT	Defective proximal pressure sensor or internal leak of the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative.
DEVICE FAULT3 REPLACE VENT	24 V supply failure.	Replace the ventilator and call your customer service representative.
DEVICE FAULT4 REPLACE VENT	Operating speed of the cooling fan not properly adjusted for the internal ambient temperature of the device.	Replace the ventilator and call your customer service representative.
DEVICE FAULT5 REPLACE VENT	Internal problem in the electrical power supply.	Replace the ventilator and call your customer service representative.
DEVICE FAULT6 REPLACE VENT	Turbine overheated because of blockage during operation.	Replace the ventilator and call your customer service representative.
DEVICE FAULT7 REPLACE VENT	Internal technical problem.	Replace the ventilator and call your customer service representative.
DEVICE FAULT8 REPLACE VENT	Inspiratory flow is constant (+/- 1 lpm) with normal turbine temperature and speed conditions.	Replace the ventilator and call your customer service representative.
DEVICE FAULT9 REPLACE VENT	POST RAM Error. RAM Read/Write does not match memory setting.	Replace the ventilator and call your customer service representative.
DEVICE FAULT10 REPLACE VENT	POST FLASH Checksum Error. Startup FLASH computed checksum does not match memory setting.	Replace the ventilator and call your customer service representative.
DEVICE FAULT11 REPLACE VENT	POST EEPROM Error. Startup EEPROM does not match memory setting.	Replace the ventilator and call your customer service representative.
DEVICE FAULT12 REPLACE VENT	POST Reference Voltage Error. 5V or 10V reference voltage error.	Replace the ventilator and call your customer service representative.
DEVICE FAULT13 REPLACE VENT	Software Version Error	Replace the ventilator and call your customer service representative.
EMPTY BATTERY	Internal battery capacity is less than 10 min. (or 2%) —battery operation overextended.	Reconnect the device to an AC power outlet, connect it to an external DC power source, or replace the battery. Reminder: the internal battery can be charged only when the ventilator connected to an AC power supply.
EXHSENS FAULT OR CIRCUIT FAULT	Leak in the patient circuit.	Check and properly connect the patient circuit connections.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
HIGH EXH VOLUME	Adjustment of the High VTE level too low.	Under the guidance of a Clinician modify the High VTE level.
	Inappropriate patient circuit.	Replace the patient circuit.
	Expiratory flow sensor not calibrated properly.	Calibrate the expiratory flow sensor (refer to section 8.1, "Replacing the Air Inlet Filter," on page 8-1).
	Defective expiratory flow sensor.	Replace the exhalation block and calibrate the expiratory flow sensor (see section 8.1, "Replacing the Air Inlet Filter," on page 8-1). Call your customer service representative.
HIGH INSP VOLUME	Adjustment of the High VTI level too low (for PSV/CPAP, PRES A/C, PRES SIMV and VOL SIMV modes).	Under the guidance of a Clinician and modify the High VTI level.
	Adjustment of the pressure level too high for the volume required (for PSV/CPAP, PRES A/C, PRES SIMV and VOL SIMV modes).	Under the guidance of a Clinician and modify the pressure level.
	Leak in the patient circuit.	Check and properly connect the patient circuit.
	Inappropriate patient circuit.	Replace the patient circuit.
	Defective flow sensor or internal leak in the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative.
HIGH MINUTE VOLUME	Adjustment of the High Min Vol level too low.	Under the guidance of a Clinician modify the High Min Vol level.
	Leak in the patient circuit.	Check and properly connect the patient circuit connections.
	Inappropriate patient circuit.	Replace the patient circuit with an appropriate one.
	Defective flow sensor or internal leak of the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative.
HIGH PRESSURE	Adjustment of High PIP too low (only for VOL A/C and VOL SIMV modes).	Under the guidance of a Clinician increase the High PIP threshold.
	Airway obstruction.	Check patient's trachea and clear the obstruction. If the filter is obstructed, replace the filter.
	Proximal pressure tube or patient circuit obstructed.	Clean the proximal pressure tube or the patient circuit or replace them.
	Coughing or other high-flow expiratory efforts.	• Silence the alarm, if necessary. • Treat patient's cough.
	Patient inspiratory resistance or compliance changes.	Have physician determine new ventilator settings.
	Defective internal circuits of the machine or pressure sensor.	Replace the ventilator and call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
HIGH RATE	Adjustment of the High Rtot level too low.	Under the guidance of a Clinician re-adjust High Rtot.
	Adjustment of the Insp Sens level too low.	Under the guidance of a Clinician adjust Insp Sens according to the patient.
	Patient's hyperventilation.	Silence the alarm and call for a medical team if the symptoms persist.
	Defective inspiratory flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
INVERSED I:E RATIO	Adjusted Insp Time inducing an inspiratory time higher than the expiratory time.	Decrease the adjustment threshold of Insp Time. **⚠ WARNING** **Ensure the Insp Time setting is compatible with the physiological requirements of the patient.**
KEYPAD FAULT CALL SERVICE *IF PERSISTS REPLACE VENT	Pressing a key for more than 45 seconds.	Press and release keys in the normal, prescribed manner. Do not press keys for 45 seconds or more.
	A key on the keyboard is stuck.	Attempt to activate each key. If unsuccessful in releasing the stuck key(s), replace the device and call your customer service representative if the situation persists.
LOW BATTERY	Internal battery capacity is less than 30 min. (or 5%)—battery operation over extended.	Immediately connect the ventilator to an AC power outlet, or connect it to an external DC power source. Reminder: the internal battery can be charged only when the ventilator is connected to an AC power supply.
LOW EXH VOLUME	Patient circuit obstructed.	Clean, unblock, and/or properly connect the patient circuit.
	Leak in the patient circuit.	Check and properly connect the patient circuit connections.
	Exhalation block missing or disconnected.	Call your customer service representative or clinician.
	Adjustment of a Low VTE threshold when the patient circuit is in a single-limb configuration.	Set the Low VTE alarm limit to OFF. **⚠ WARNING** **If exhaled volume monitoring is required, use the double-limb circuit for exhaled tidal volume or minute volume monitoring.**
	Inappropriate patient circuit.	Replace the patient circuit with an appropriate one.
	Expiratory flow sensor not properly calibrated.	Call your customer service representative or clinician.
	Defective expiratory flow sensor.	Replace the defective component(s) and Call your customer service representative or clinician.
	Adjustment of the Low VTE level too high.	Under the guidance of a Clinician modify the Low VTE level.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
LOW INSP VOLUME	Adjustment of the Low VTI level too high (for PSV/CPAP, PRES A/C, PRES SIMV and VOL SIMV modes)	Under the guidance of a Clinician modify the Low VTI level.
	Adjustment of the pressure level not enough to reach the volume required (for PSV/CPAP, PRES A/C, PRES SIMV and VOL SIMV modes).	Under the guidance of a Clinician modify the pressure level.
	Patient circuit obstructed or disconnected.	Clean, unblock, and/or reconnect the patient circuit.
	Inappropriate patient circuit.	Replace the patient circuit.
	Defective flow sensor or internal leak in the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative.
LOW MINUTE VOLUME	Adjustment of the Low Min Vol level too high.	Under the guidance of a Clinician modify the Low Min Vol level.
	Inappropriate patient circuit.	Replace the patient circuit with an appropriate one.
	Patient circuit obstructed or disconnected.	Clean, unblock, and/or properly connect the patient circuit.
	Defective flow sensor or internal leak of the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative.
LOW PRESSURE DISCONNECT *IF PERSISTS REPLACE VENT	Adjustment of Low PIP too high.	Under the guidance of a Clinician decrease the Low PIP threshold.
	Leak or loose connection in the patient circuit.	Check the patient circuit connections to the ventilator; examine all connections for leakage and tightness. Replace the patient circuit if necessary.
	Inappropriate patient circuit.	Replace the patient circuit.
	Defective internal circuits of the machine or pressure sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
OCCLUSION CHECK CIRCUIT *IF PERSISTS REPLACE VENT	Patient circuit obstructed.	Clean, unblock, and/or properly connect the patient circuit.
ON INTERNAL BATTERY	12 – 30 VDC power supply cut off when there is no AC (“mains”) power supply.	Cancel the alarm then check the supply wiring and/or the effective availability of voltage on the external source.
	Ventilator’s current-limiting fuse blown.	Replace the ventilator and call your customer service representative.
POWER FAULT REPLACE VENT	Internal problem in the electrical power supply.	Replace the ventilator and call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
POWER SUPPLY LOSS (without message)	Electrical power supply cut off by the main switch when ventilation is in progress.	Press the I/O switch to restore electrical power to the ventilator and allow ventilation to continue. To stop ventilation, press the VENTILATION ON/OFF key for three seconds (refer to chapter 5, "Operating Procedures").
	The internal battery that supplies the ventilator is entirely discharged.	Immediately connect the ventilator to an AC power outlet or an external DC power source; otherwise, use an alternate device to ventilate the patient.
REMOTE ALARM FAULT	Nurse Call is disconnected.	Connect the Nurse Call cord to the ventilator.
	Relay control voltage problem.	Call for the maintenance technician and carefully monitor the patient to detect possible alarm triggering.
SOFTWARE VERSION ERROR	Incorrect software version detected.	Call your customer service representative.
SPKR FAULT1, SPKR FAULT2 REPLACE VENT	Defective internal buzzers.	Replace the ventilator and call your customer service representative.
	Internal technical problem that prevents the very high priority "POWER SUPPLY LOSS" alarm from triggering.	• Call your customer service representative. • Connect the ventilator to its AC power supply. Ensure that the internal battery is completely charged. • Ensure that the protective cover over the I/O switch located on the rear of the device is intact and functioning properly. This cover helps prevent accidental pressing of the I/O switch and stoppage of the ventilation. • Ensure that the device is stabilized.
SPKR FAULT3 REPLACE VENT	Internal technical problem that prevents the battery from correctly charging.	Replace the ventilator and call your customer service representative.
SPKR FAULT4 REPLACE VENT	Internal technical problem that prevents the battery warning buzzer from operating.	Replace the ventilator and call your customer service representative.

3.8.2 Other Problems

Table 3-3 provides other possible ventilator problems, causes, and corrective actions.

WARNING

- **If the device is damaged, its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.**
- **If you cannot determine the cause of the problem, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.**

Note:

Speaker and battery alarms may occur when the unti is first powered on after the internal battery has been completely drained. Connect to an AC power source and recycle power.

Table 3-3. Additional Problems and Corrective Actions

Problem	Possible Causes	Corrective Actions
No access to the waveforms	Display waveform set to NO in Preference menu.	Set Display waveform to YES in Preference menu.
The screen backlight never switches off during ventilation	Backlight set to NO in Preference menu.	Set Backlight to YES in Preference menu.
Alarm sound level too low or too high	Adjustment of the alarm sound level is incompatible with the patient's environment.	Re-adjust sound level.
Poor visibility of the displays	Contrast adjustment is incompatible with the luminosity of the environment.	Re-adjust contrast.
Unusual display on the screen	Problem with the display unit.	Call your customer service representative if the problem persists. **CAUTION:** Do not expose the ventilator to direct radiation from the sun.
The ventilator does not operate after pressing I/O switch	No external power source and the internal battery is completely discharged.	Connect the ventilator to the AC power source.
Light noise	Turbine noise.	Replace the ventilator and call your customer service representative.
Whistling noise or vibrations	Filter and/or turbine silencer deteriorated.	Replace the ventilator and call your customer service representative.
	Valve membranes damaged.	Replace the ventilator and call your customer service representative.
Excessive heat emitted	Obstruction of main or secondary air inlets of the casings.	Remove obstructions from all blocked ventilator air inlets and outlets.
Condensation inside the device	Liquid entered the device.	Replace the ventilator and call your customer service representative.

4 Installation and Assembly

WARNING

- **The device must not be connected to anti-static tubes, conduits, or electrical conductors.**
- **A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is recommended.**

4.1 Installing the Ventilator

To install your Puritan Bennett 540™ Ventilator correctly we recommend that you proceed in the following manner:

- Choose an area where air can circulate freely; avoid proximity to loose fabrics such as curtains.
- Avoid direct exposure to sunlight.
- Set the ventilator on a flat and stable surface so that its feet are all in contact with the surface. The ventilator may operate in any position, provided that the air inlets are not obstructed and the device cannot fall and possibly cause damage and/or personal injury.

WARNING

- **To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.**
- **Do not place the ventilator in a position where a child could reach it or in any position that might cause it to fall on the patient or someone else.**
- **Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.**
- **Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.**
- **If the room temperature at the device's installed location is greater than 95 °F (35 °C), the flow supplied at the device outlet may exceed 106 °F (41 °C). This may lead to undesirable effects, such as excessive discomfort, for the patient. In this case, the device should be used with additional precautions, including installation in a cooler location.**
- **To reduce the risk of fire, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and heaters) away from the ventilator and its oxygen supply and hoses.**
- **Even if the "INTERNAL BAT" charging indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 104 °F (40 °C) because of the battery's internal heat safety device.**

Caution

- The use of any accessory other than those specified by Puritan Bennett, may lead to an increase in electromagnetic emissions or a decrease in the equipment's insulation against electromagnetic emissions.
- The Puritan Bennett 540™ Ventilator requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations stated in Appendix A, "Specifications". In particular, the use of nearby mobile and portable communications equipment using radio frequencies (such as mobile telephones) or other systems exceeding the levels set in the IEC 60601-1-2 standard may affect the ventilator's operation.

4.2 Connecting to External AC Power

Any of four power sources: AC power, 12 – 30 VDC power, Internal Battery power, or Auxiliary DC car adapter (cigarette lighter) can be used to power the ventilator. But when AC power is available, the ventilator will automatically select AC power as its operating power source.

WARNING

- **The power supply to which the ventilator is connected (both AC and DC) must comply with all current and applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation.**
- **Never connect your ventilator to an electrical outlet controlled by a wall switch because the power may be inadvertently turned off.**
- **To be held correctly, the AC power cable must be fitted into the cable holder incorporated in the battery access cover and located under the AC power socket. Refer to the following instructions.**

Caution

- Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.
- Ensure that the AC power cable is in perfect condition and not compressed.
- Do not leave power cables lying on the ground where they risk being stepped on and damaged.

To prevent accidental disconnection of the AC power cable, use the power cable holder (Figure 4-1, item 1) that is inserted into the notch (Figure 4-1, item 2) of the battery cover (follow the instructions on the next page).

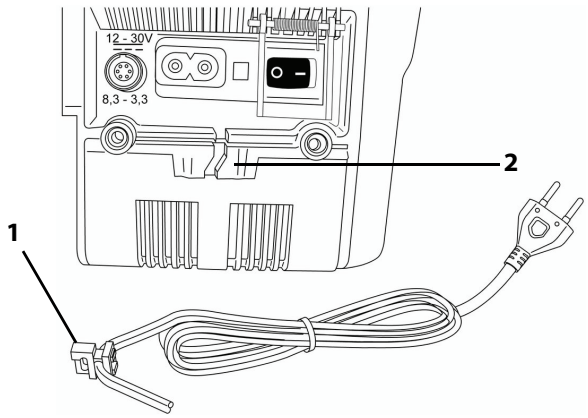


Figure 4-1. AC Power Cable Holder

To secure the AC power cable, proceed as follows:

1. Insert the power cable holder (Figure 4-2, item 1) into the notch of the battery cover.

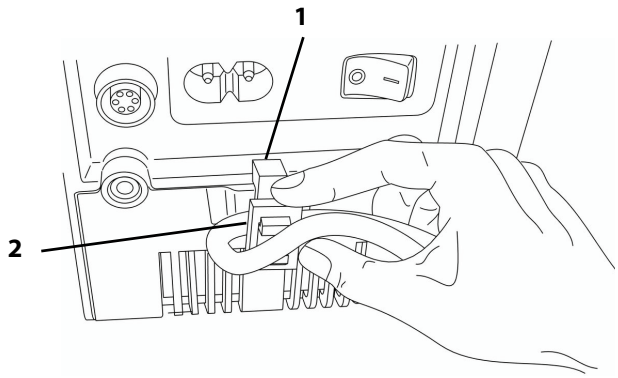


Figure 4-2. Inserting the Power Cable Holder Into the Notch

2. Push the AC power cable into the power cable holder (Figure 4-2, item 2).
3. Connect the female end of the ventilator's AC power cable to the AC connector on the back of the ventilator.

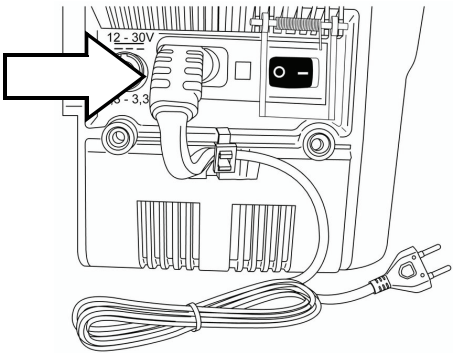


Figure 4-3. Power Cable Connected to the Ventilator

4. Connect the male end of the AC power cable to the AC power outlet.
   - The **AC POWER** ~ indicator on the top left corner of the ventilator illuminates.
   - The **INTERNAL BAT** indicator ▭ flashes while the battery charges and then turns off when the battery is fully charged.

   Refer to Figure 4-4 on page 4-4.

If the AC power cable becomes disconnected or the AC power source fails, an "AC POWER DISCONNECTION" alarm signals an automatic switch to the external DC power source (if the DC power cable is connected) or to the ventilator's internal battery.

One of three power indicators, located on the upper-left of the ventilator's front panel, illuminates to signal which of the three possible power sources are currently in use by the device (refer to Figure 4-4).

Note:

The only time the AC POWER and INTERNAL BAT indicators are illuminated at the same time is when the ventilator is connected to an AC supply and the battery is charging (INTERNAL BAT indicator is flashing).

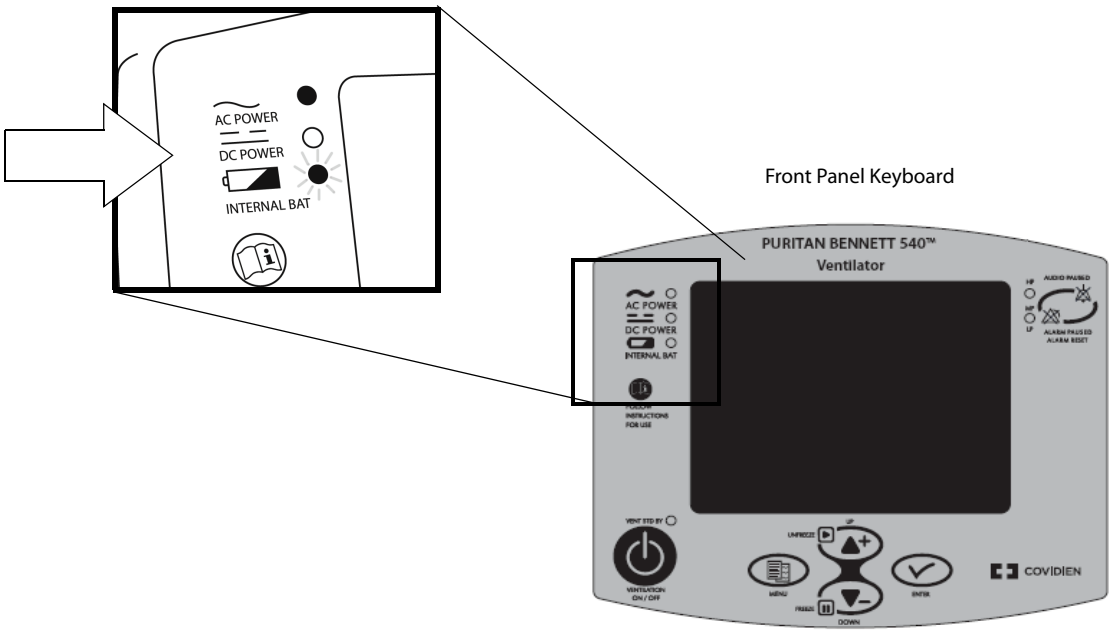


Figure 4-4. Power Indicators

To disconnect the AC power cable:

1. Disconnect the AC power cable from the AC power outlet.
2. Disconnect the AC power cable from the ventilator's AC connector at the rear of the device.
3. Grasp the AC power cable at the level of the power cable holder and turn the cable counterclockwise while lifting it upwards and out of the holder.

4.3 Connecting to an External DC Power Source

WARNING

- **The use of the device on an external 12 – 30 VDC power source does not allow charging of its internal battery. Ensure that the internal battery is fully charged before connecting the DC power cable.**
- **When using a car auxiliary adapter (cigarette lighter) ensure the car has been started prior to plugging in the ventilator's DC adapter.**

Whenever AC power is unavailable, the ventilator can operate from a continuously powered external 12 – 30 VDC power source via a DC power cable (Figure 4-5, item 1) that connects to the ventilator's rear panel DC power input connector (Figure 4-5, item 2). The DC power cable is optional; refer to Appendix E, "Parts and Accessories", for more information. It is also possible to use the DC auxiliary port (cigarette lighter) in a car as a power source as. Ensure the car's engine is started prior to connecting the ventilator.

Note:

- When away from a wall power source or using an external battery, carry at least two external battery packs with the ventilator.
- An alternative means of ventilation should always be available, particularly when the patient is in transit or away from wall power.
- While using the ventilator on external battery power it is vital that a qualified caregiver (capable of providing the necessary corrective actions in the event of alarm conditions) is present.

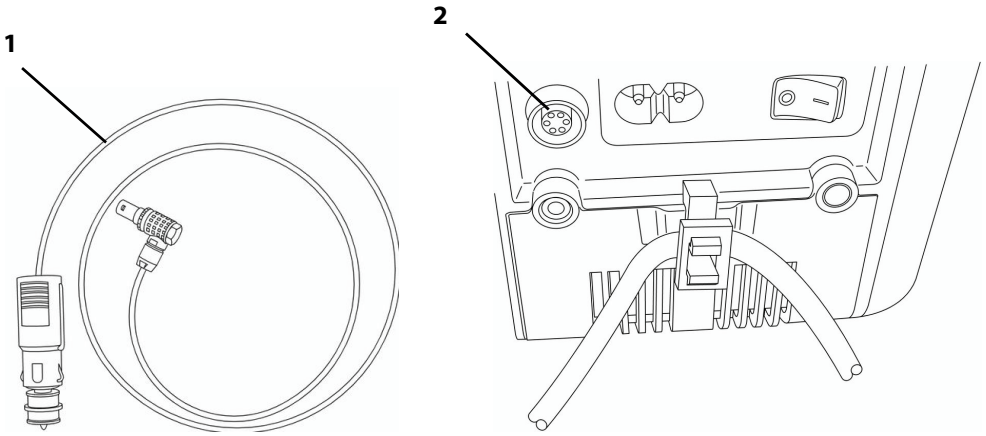


Figure 4-5. Connecting the Ventilator to an External DC Power Source

Caution

Connect the external DC power source by first connecting the power cable to the ventilator and then to the external DC source. Follow the reverse procedure to disconnect the device from the external DC power source.

To connect the DC power cable to the ventilator, proceed as follows:

1. Line up the red marker dot on the ventilator's DC power connector with the marker on the DC power cable (Figure 4-6, item 1).

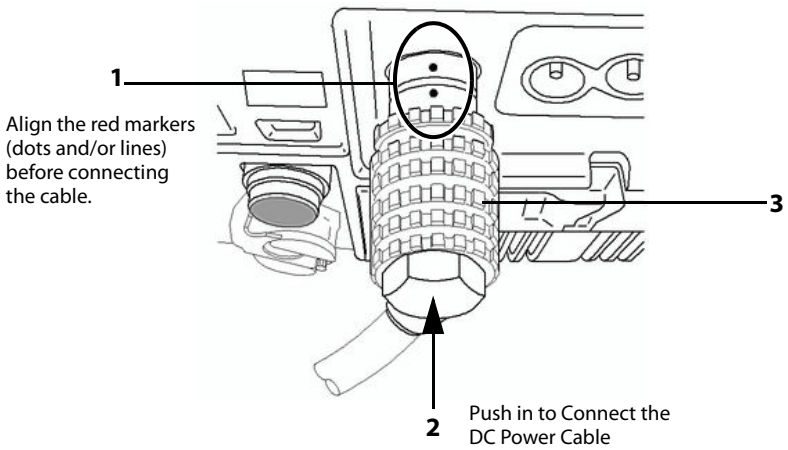


Figure 4-6. Connecting the DC Power Cable to the Ventilator

2. Push the DC power cable onto the ventilator's DC power connector (Figure 4-6, item 2).
   - You will hear a locking "click".
   - The **DC POWER** indicator on the top left corner of the ventilator illuminates (see Figure 4-4).

To disconnect the DC power cable from the ventilator, slide the locking ring (Figure 4-6, item 3) back and pull the plug away from the ventilator's rear panel to disengage it.

An "ON INTERNAL BATTERY" alarm signals an automatic switch to the internal battery in case the external DC power source fails or becomes disconnected.

4.4 Patient Circuit

WARNING

- **For pediatric use, ensure that the patient circuit type fits, and, in all respects, is suitable for use with a child. Use a pediatric circuit for patients that weigh under 53 lb. (23 kg).**
- **If exhaled volume monitoring is required (such as ventilator dependant patients), use the double-limb circuit for exhaled tidal volume or minute volume monitoring. In this configuration, the expired volume is monitored to ensure correct patient ventilation and identify any leaks or other problems in the patient circuit. Similarly, the Low VTE setting must be properly set to warn in the event of patient suffocation.**
- **The ventilator and patient circuit should always be placed so as not to hinder the patient's movements, prevent accidental disconnection, and reduce the risk of patient strangulation by the circuit.**
- **The ventilator and patient circuit should always be placed so as to provide a secure, comfortable fit for the patient.**
- **The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection, and to minimize the risk of patient strangulation.**

WARNING

- **The patient circuit is intended for single use by a single patient and should be changed according to the manufacturer's recommendations. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator).**
- **Before assembling or reassembling the patient circuit—and on a daily basis—inspect the hoses and all other components to ensure that there are no cracks or leaks and that all connections are secure.**
- **To ensure correct performance of the ventilator, the patient circuit used must be one of those recommended by Puritan Bennett in this manual. The connections of the outlet towards the patient and the return to the exhalation block (with a double limb circuit) must be made with a 3.6 feet (1.10 m) to 6.6 feet (2.00 m) long tube (between the ventilator and the patient). The tube must conform to applicable standards and be fitted with Ø 22 mm terminals that also conform to standards. Ensure that the length and the internal volume of the patient circuit are compatible with the patient's tidal volume: a ringed tube Ø 22 mm for adults, and a ringed tube Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.**
- **Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.**
- **Users must always possess an additional circuit and valve while using the Puritan Bennett 540™ Ventilator.**

4.4.1 Choosing the Patient Circuit Type

Single limb circuits are used with breathing modes where spirometry measurements are not required, and double limb circuits are used with breathing modes where spirometry is required. Be sure to choose the appropriate circuit in the menu preferences.

4.4.2 Installing the Patient Circuit

The patient circuit is mounted depending on the setup of the circuit used and the accessories used.

The following procedures describe the installation of the patient circuit with a humidifier. To add other accessories, refer to the installation instructions for the specific accessories used.

To connect a single limb circuit do the following and refer to Figure 4-7:

1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.
2. Install the bacteria filter (item 1) on the TO PATIENT outlet port, as shown.
3. Attach one end of the short circuit tubing (item 4) to the filter (item 1).
4. Attach the other end of the circuit tubing (item 4) to the inlet port of the humidifier (item 2).
5. Place a water trap (item 3) between the outlet port and the inlet ports of the exhalation valve (item 5).
6. Ensure the exhalation valve (item 5) is placed at the level of the patient.
7. Connect one end of the proximal pressure tubing (item 6) to the proximal pressure port on the exhalation valve (item 5) and the other end onto the ventilator patient pressure port (item 8).
8. Connect one end of the exhalation valve tubing (item 7) to the exhalation valve port on the exhalation valve (item 5) and the other end onto the ventilator exhalation valve port (item 9).

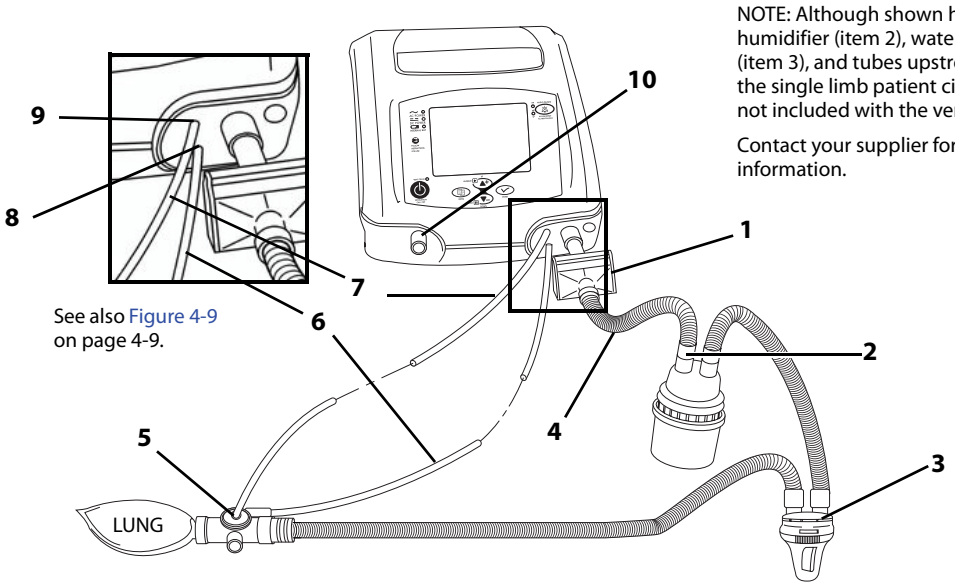


Figure 4-7. Single Limb Patient Circuit

9. To protect the exhalation port (as it will not be used in this configuration), place the cap (if provided with the breathing circuit) over the exhalation port opening (item 10).

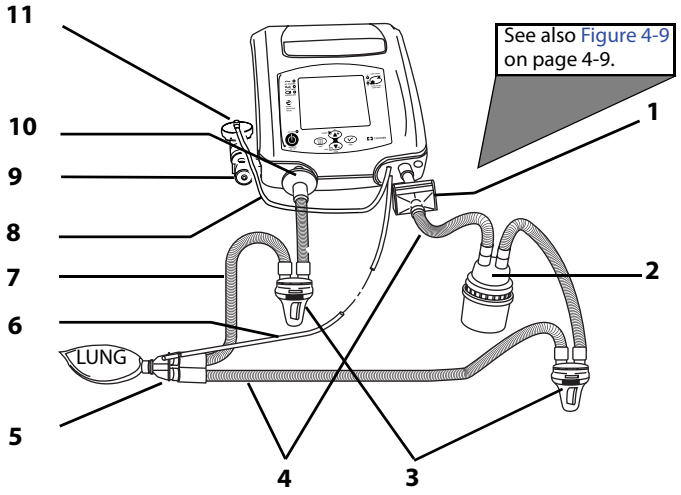
To connect a double limb circuit, do the following and refer to Figure 4-8:

1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.
2. Install the bacteria filter (item 1) on the TO PATIENT outlet port.
3. Attach one end of the short circuit tubing (item 4) to the filter (item 1).
4. Attach the other end of the circuit tubing to the humidifier's inlet port (item 2).
5. Place a water trap (item 3) between the outlet port of the humidifier and the patient wye (item 5) on the double limb circuit.
6. Place a water trap (item 3) between the patient wye and the inlet port of exhalation filter (item 5).
7. Connect one end of the small proximal pressure tubing (item 6) as close as possible to the patient at the level of the double limb patient wye circuit connection (item 5) and the other end on the ventilator patient pressure port.

Note:

When shipped, the proximal pressure tube may already be connected to the patient wye. If so, simply verify that the connection is secure and the tube shows no signs of damage, kinks, or obstructions.

8. Ensure that the water trap (item 3) on the expiratory limb of the patient circuit (item 7) is securely installed between the patient wye (item 5) and the exhalation valve (item 9).



NOTE: Although shown here, the humidifier (item 2), water traps (item 3), and their connecting tubes are not included with the patient circuit or ventilator. Contact your supplier for more information.

Figure 4-8. Double Limb Patient Circuit

9. Place the exhalation valve (item 9) on the exhaust port.
10. Place a bacteria filter (item 10) between the exhalation valve (item 9) and the inlet port of the ventilator exhalation block (item 11).
11. Connect one end of the small exhalation valve tubing (item 8) to the exhalation valve port of the exhalation valve (item 11) and the other end onto the ventilator exhalation valve port.

Figure 4-9 shows details of the connections of the proximal pressure tube (Figure 4-8, item 6) and the exhalation valve tube (Figure 4-8, item 8).

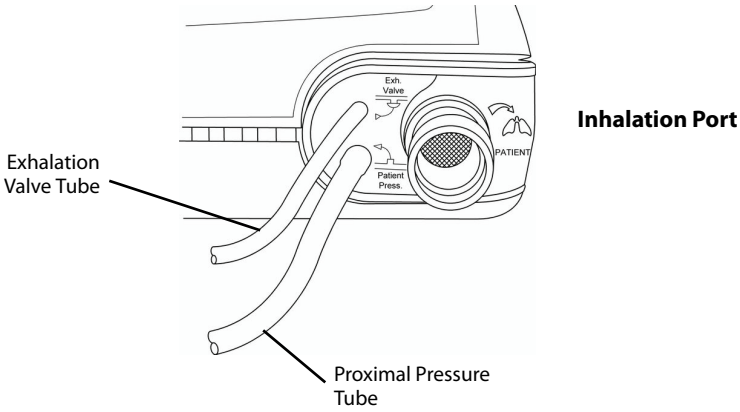


Figure 4-9. Close-up of Exhalation Valve Tube and Proximal Pressure Tube

For both types of circuits, shown previously, you should connect the end of the proximal pressure tube as close as possible to the patient (at the mask or cannula entry, if possible) so that the ventilator can account for all load losses due to the circuit and its potential accessories. If this is not possible, it is best to modify the LOW PRESSURE DISCONNECT triggering threshold by doing one of the following: set the high VTI alarm limit for pressure modes or set low VTE alarm limit for all ventilation modes if using a dual limb circuit.

WARNING

.In the SIMV mode we recommend using a double limb circuit and leaving the VTE Min setting active in the event that pressure losses are present on the patient circuit downstream from the proximal pressure link. This is because in such cases the "PATIENT DISCONNECTION" alarm would not be systematically activated in case of a disconnection of the circuit.

As a reminder: Ensure that the length and the internal volume of the patient circuit are compatible with the tidal volume: ringed tube Ø 22 mm for adults and ringed tube Ø 15 mm for pediatric patients with tidal volumes lower than 200 ml. Use, if necessary, a 22F-15M link on the outlet and a 15M-22M link on the expiratory block for a double limb circuit.

WARNING

- **When a nose mask or face mask is used in Non-Invasive Ventilation (NIV), the mask must NOT contain an expiration aperture or exhaust port (no leakage).**
- **The level of inspiratory resistance of the circuit and accessories (bacterial filter, humidifier, and so on) must be as low as possible. Settings—particularly the LOW PRESSURE DISCONNECT alarm, High inspired volume (High VTI), and Low inspired volume (Low VTI) settings—must be periodically adjusted according to changes in the patient circuit resistance—especially when filters are replaced.**
- **Resistance of the exhalation valve and accessories (water traps, filters, etc) must be as low as possible.**
- **The exhalation valve must allow rapid discharge of the circuit pressure. Ensure that the exhalation valve is always clean and its evacuation aperture (exhaust port) is never obstructed.**
- **Do not start ventilation until you ensure that the device is suitably assembled, and that there is proper clearance all around the unit. Ensure that the air inlet filter is properly installed and is not obstructed. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.**
- **Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.**

4.5 Filters

WARNING

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. Replace the filter as often as necessary to maintain cleanliness—even before the recommended replacement period is over. This is critical particularly when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.

The ventilator features two filter types:

- air inlet filter
- bacteria filter

Air Inlet Filter

Consisting of foam and fine particle filter media and located at the rear of the ventilator, this filter cleans the air as it enters the ventilator. Refer to the figure below.

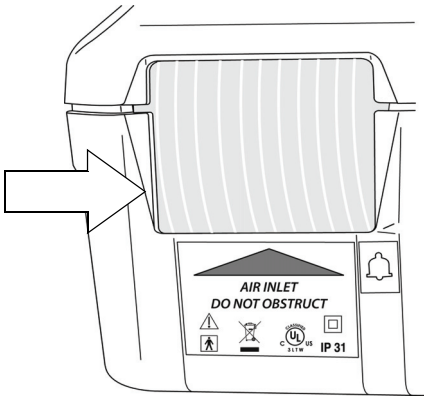


Figure 4-10. Air Inlet Filter

Caution

The air inlet filter is not reusable. Do not attempt to wash, clean, or reuse the filter.

Bacteria Filter

It is highly recommended that you install an bacteria filter (see Figure 4-11) on both single and double limb circuits. In a double limb configuration, two bacteria filters are used: one at the port labeled TO PATIENT, and the other at the port labeled FROM PATIENT.

- Connected to the TO PATIENT port:

  This filter protects the ventilator from contamination by the patient (primarily, rebreathed air that contains a high concentration of carbon dioxide). Refer to Figure 4-8, item 1.

- Connected to the FROM PATIENT port:

  This filter protects the internal expiratory flow sensor from any obstruction from the gases exhaled by the patient. Refer to Figure 4-8, item 10.

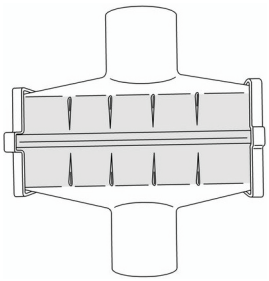


Figure 4-11. Bacteria Filter

Refer to the manufacturer's instructions for more information about the use and maintenance of the bacteria filter(s).

4.6 Humidifier

The humidifier (Figure 4-12) adds moisture (water vapor) and warms the air in the patient circuit. It is inserted into the patient circuit between the main outlet and the patient (refer to Figure 4-7 and Figure 4-8).

WARNING

- **During invasive ventilation, the patient's upper airways may become dry and irritated, causing discomfort. For this reason, the use of a humidifier is strongly recommended.**
- **Always position any humidification device so that it is at a lower height than both the ventilator and the patient. Use water traps, if necessary, to limit water flow towards the ventilator and the patient and periodically empty these water traps.**
- **If a heated humidifier is used, you should always monitor the temperature of the air delivered to the patient. Air that becomes too hot may burn the patient's airway.**
- **Consult with your Customer Support representative before attempting to use a heated humidifier.**
- **Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.**

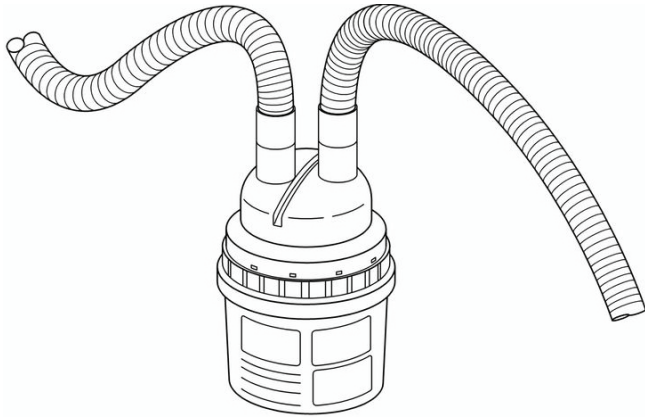


Figure 4-12. Humidifier

When a humidification device is used, any condensation that forms in the patient circuit is collected in the water trap. If you notice any moisture in the patient circuit, you need to replace the wet circuit components with dry ones.

Refer to the humidification device's instruction for information on operating, cleaning, and sterilizing the humidifier.

4.7 Exhalation Block

WARNING

- **The exhalation block is for single use by a single patient: ②. It may be periodically cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when the ventilator is in continuous use change it every three months.**
- **Each time an exhalation block is installed, the expiratory flow sensor must be recalibrated before using the ventilator.**

Caution

Ensure that the exhalation block has been completely dried after it is cleaned.

The exhalation block requires calibration and should only be removed or cleaned by qualified personnel.

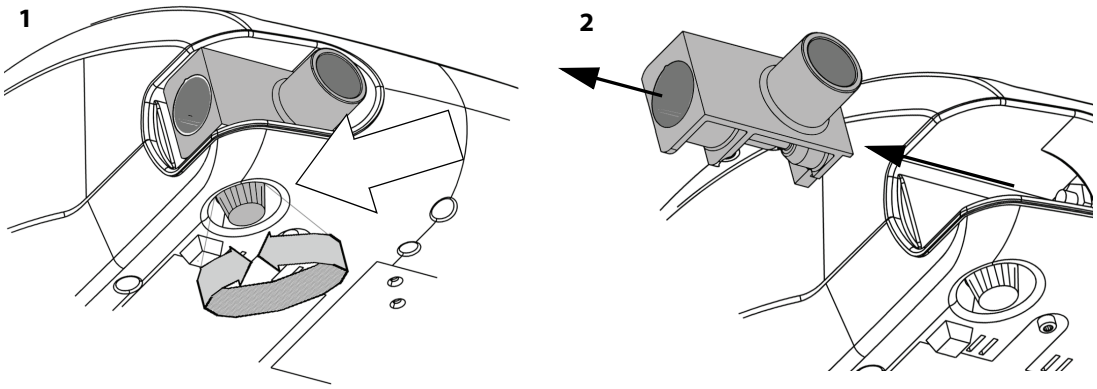


Figure 4-13. Removing the Exhalation Block

4.8 Oxygen

WARNING
The ventilator must not be used with flammable anesthetic substances.

4.8.1 Administering Oxygen

WARNING
Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, oxygen therapy should always be used with the utmost care; too high an oxygen flow is likely to lead to serious complications for the patient.

Oxygen administered to the patient is introduced from an external source into the machine through the oxygen connector at the rear of the ventilator. It is then integrated into the total volume of delivered air. It is recommended that the oxygen ports on the ventilator be capped when not in use.

The specific oxygen flow to the patient depends on the physiological characteristics of the patient and the ventilator settings.

The oxygen flow setting should be adjusted for *each* patient and established in relation to a *calibrated* oxygen monitor measurement. Since the factors that affect administered oxygen flow may change over time, you must ensure that these settings always correspond to the *current* oxygen therapy objectives specified by the physician.

Note:

To monitor patient Oxygen levels use an external sensor/alarm.

WARNING

- **To avoid injury to the patient and/or possible damage to the ventilator: before using the ventilator, use a flow meter (flow regulator) to regulate the oxygen supply to specifications before connecting the ventilator to the oxygen supply.**
- **Ensure that the oxygen supply pressure to the machine never exceeds 7.25 psi (49.99 kPa) or a flow of 15 lpm. Refer to Table A-17 on page A-12.**
- **ThePuritan Bennett 540™ does not include an oxygen analyzer. Always measure the delivered oxygen with a calibrated oxygen analyzer that features a high and low concentration alarm in order to ensure that the prescribed oxygen concentration is delivered to the patient.**

4.8.2 Connecting the Oxygen Supply

WARNING

- **Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.**
- **The hose connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.**

A connector (Figure 4-14, item 1) for an external low pressure oxygen source is available at the rear of the ventilator. It is essential that you also use the special coupler (item 2) supplied with the ventilator to attach the external low pressure oxygen source to the connector. The connector is also fitted with a non-return airtight valve system. The non-return airtight valve system includes a stud (item 3) and a locking tab (item 4).

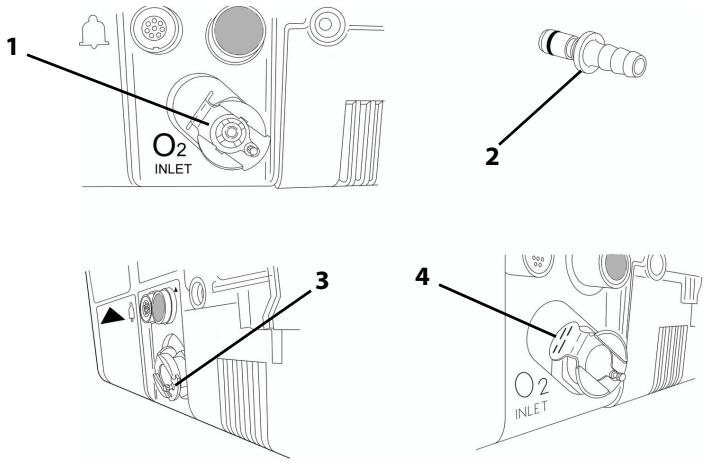


Figure 4-14. Rear Panel Oxygen Connector

Caution

- Before connecting the oxygen supply, ensure that the stud on the oxygen connector (Figure 4-14, item 3) is protruding outwards.
- Inspect the oxygen coupler (Figure 4-15, item 2) before use to ensure it has its black O-ring attached and in good condition. Do not use an oxygen coupler with a missing, damaged, or worn O-ring.

To connect the oxygen supply system to the ventilator, proceed as follows and refer to Figure 4-15:

1. Inspect the oxygen supply's connector (Figure 4-15, item 1) to ensure that connector's black O-ring (item 2) is not missing.
2. Push the oxygen supply's oxygen connector (item 1) into the ventilator's oxygen connector (Figure 4-15, item 3).
   - the ventilator's oxygen connector's locking stud (item 4) retracts.
   - the ventilator's oxygen connector's locking tab (item 5) is released, ensuring that the oxygen connection is locked and secured in place.

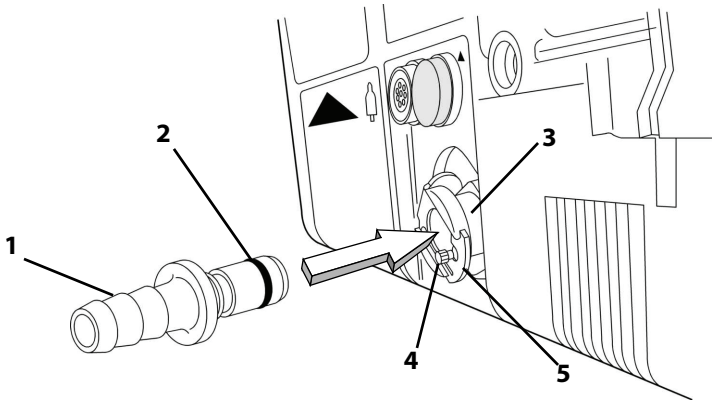


Figure 4-15. Connecting the Oxygen Supply System

To disconnect the oxygen supply system from the ventilator, proceed as follows:

1. Stop the oxygen flow from the oxygen supply.
2. Press the locking tab of the ventilator's oxygen connector, as shown in Figure 4-16, to unlock the oxygen connection.

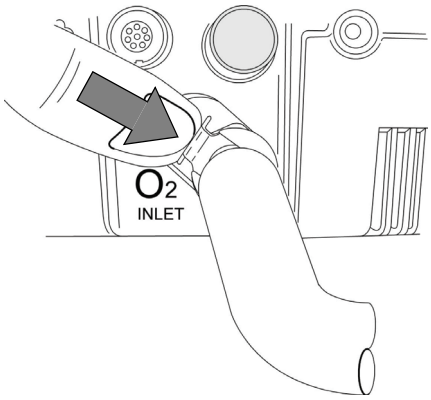


Figure 4-16. Disconnecting the Oxygen Supply System

3. Disconnect the oxygen supply's oxygen connector by pulling it towards you.

   The ventilator's oxygen connector's locking stud (Figure 4-15, item 2) will then extend outwards, which is required before the oxygen connector can be reconnected.

WARNING

- **Never use the ventilator with an unregulated/unadjustable oxygen source.**
- **The connecting hose between the ventilator and the O_2 source must be designed for use exclusively with medical-grade oxygen. Under no circumstances should this hose be modified by the user, and it must be installed without the use of lubricants.**
- **Disconnect the oxygen supply's oxygen connector from the ventilator whenever the oxygen supply is not in use or the connector is not connected to a leak-proof, external oxygen supply. Otherwise, a leak may occur and compromise the performance of the ventilator.**
- **In the event of an oxygen leak, immediately shut down the oxygen supply at its source and keep away from any incandescent source or other possible sources of ignition. Thoroughly air the room to bring the oxygen concentration down to normal.**
- **To prevent any interference with the internal sensors of the Puritan Bennett 540™ Ventilator, do not install a humidifier upstream of the ventilator.**

Caution

- The oxygen supply hose ages and degrades even when it not in use and should be replaced periodically. The exhalation date of the hose may be indicated on the back of the hose's end piece.
- The oxygen supply must be shut off whenever ventilation is interrupted. Allow the ventilator to continue for a few cycles without oxygen whenever ventilation is stopped or started.

The external oxygen source must also have independent means of flow adjustment from the ventilator.

4.9 Mounting the Ventilator on a Wheelchair

WARNING

- **Do not rely solely on the ventilator's internal battery to sustain the ventilation. Always provide an alternative external power source.**
- **Due to its limited internal battery's reserve capacity, the ventilator should only be operated occasionally while powered by its internal battery. Ensure that the internal battery never becomes fully discharged.**
- **Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.**
- **Fluid or moisture of any kind must not be allowed to seep inside the ventilator. Particular areas of vulnerability include the air inlet filter and the cooling apertures located in the side, rear, and bottom panels of the ventilator.**
- **If exhaled tidal volume or exhaled minute volume measurements are required to ensure correct patient ventilation a double limb patient circuit configuration must be used in order to detect leaks. In this case, both the High and Low VTE alarm parameters must be properly set to warn in the event of patient suffocation.**
- **To minimize the risk of damage, you must use the ventilator's Dual Bag to transport the ventilator.**
- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. Replace the filter as often as necessary to maintain cleanliness—even before the recommended replacement period is over. This is critical particularly when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.**

Caution

Before using the ventilator on the internal battery, ensure that it is charged and that the charge holds (refer to chapter 6, "Internal Battery").

The Dual Bag accessory consists of a carrying bag that allows the Puritan Bennett 540™ Ventilator to be both mounted onto a wheelchair and carried as a backpack (see Figure 4-17).

Refer to the Dual Bag's instructions for further information.

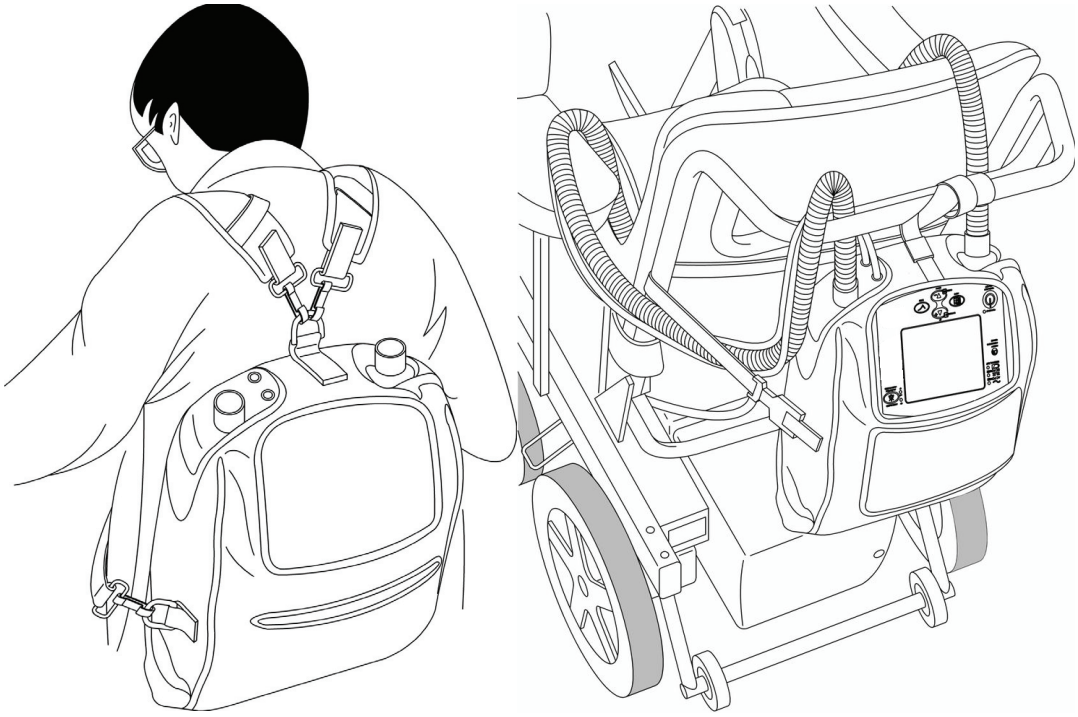
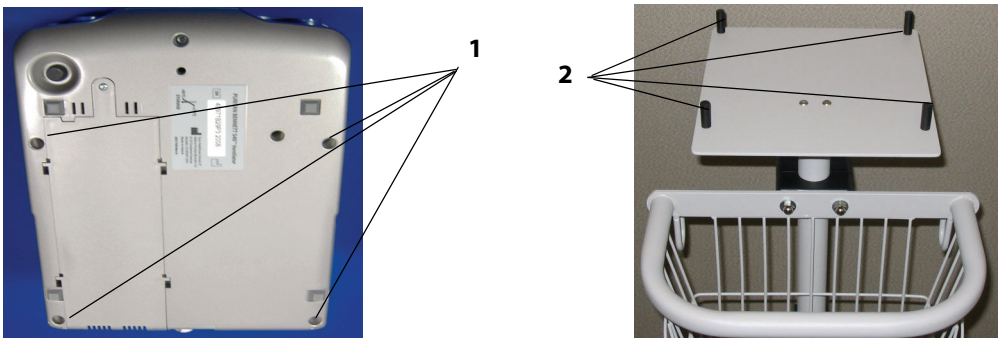


Figure 4-17. Using the Dual Bag Accessory

4.10 Mounting the Ventilator on the Utility Cart

Match the mounting holes (item 1) on the bottom of the Puritan Bennett 540™ Ventilator to the mounting studs (item 2) on the top of the utility cart platform.



4.11 Connecting the Nurse Call Cable

Connect the Nurse Call cable (Figure 4-18, item 1) to the Nurse Call Monitor Connector (item 2).

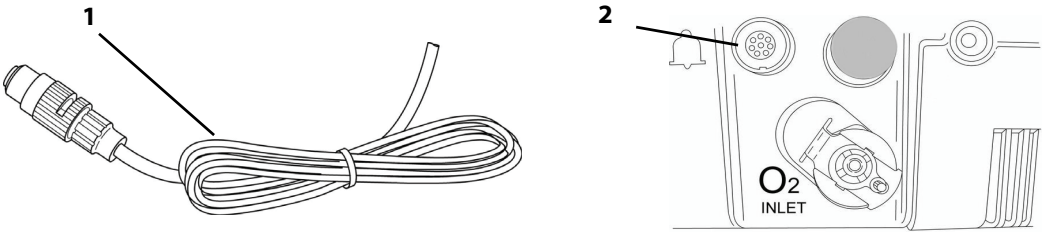


Figure 4-18. Connecting the Nurse Call Cable

WARNING

- **Before using the Nurse Call system, ensure that its connections are secure and it operates properly. For more information, contact Puritan Bennett.**

Caution

- To connect the Puritan Bennett 540™ Ventilator to a nurse call device, first contact Puritan Bennett to verify device compatibility and to obtain a suitable connection cable.
- Do not use Nurse Call devices that operate based on the closure of an electrical circuit, because the devices often do not take into account possible cable disconnection or a total loss of power. Ensure that the Nurse Call device is always connected to the ventilator.

The Nurse call function provides for remote alerts of ventilator alarm conditions (for example, when the ventilator is used in an isolation room), and features the following:

- The ventilator signals an alarm using a normally open (NO) or a normally closed (NC) signal.
- A remote alarm is activated when an alarm condition occurs, unless either of the following is true:
  - The audio paused function is active.
  - The ventilator power switch is OFF.
- The remote alarm port is an 8-pin female connector; allowable current is 100mA at 24VDC(max).

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5 Operating Procedures

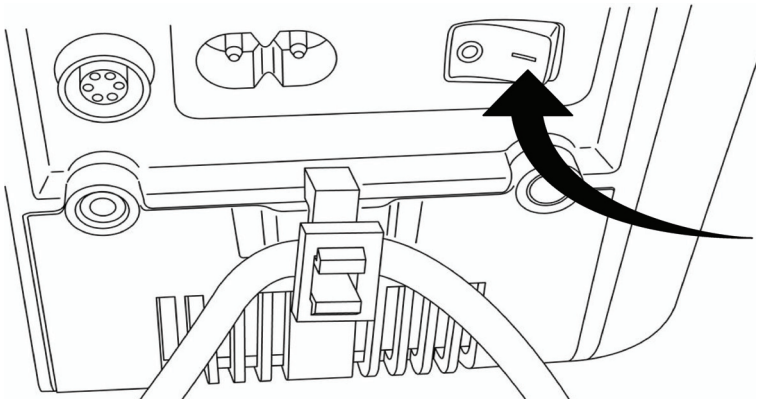
5.1 Turning on The Ventilator

Caution

After storage of the Puritan Bennett 540™ Portable Ventilator in an atmosphere that differs significantly in temperature from where it is installed—typically, ± 36 °F (20 °C)—stabilize the device at room temperature for at least two (2) hours prior to starting it.

To turn the ventilator on, do the following:

Set the **I/O** switch (a covered, rocker-type switch located at the rear of the ventilator) to the **I** position, as shown in Figure 5-1 below.



NOTE: I/O switch cover not shown here.

Figure 5-1. Turning on the Ventilator

The following events occur:

- The ventilator is powered on.
- A Power On Self Test (POST) is carried out (when plugged in to an AC power source): the front panel indicators flash (except for the indicator showing the type of power supply in use, which remains lit) and the audible alarms briefly sound.
- The display's backlight turns on.
- The PURITAN BENNETT logo is momentarily displayed.
- The blue **VENT STDBY** indicator to the right of the **VENTILATION ON/OFF** key illuminates, indicating the device is in standby mode.
- A Welcome Menu screen is displayed for about five (5) seconds, which includes the machine counter and the patient counter, as shown in Figure 5-2.

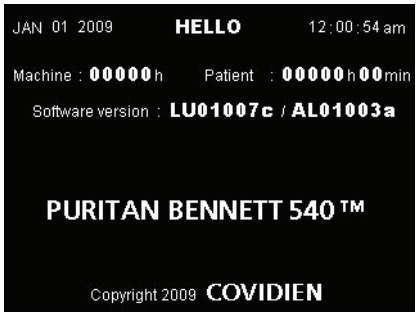


Figure 5-2. Welcome Menu Screen

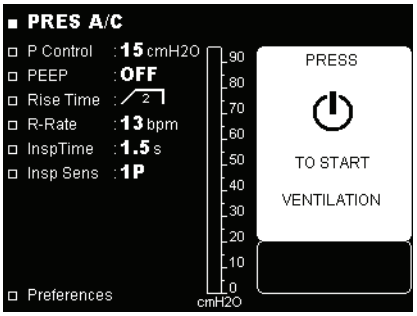
Note:

- If the ventilator had been previously stopped by use of the **I/O** switch while ventilation was in progress, the ventilator starts directly in ventilation mode and does not show the Welcome Menu screen.
- The Alarm, Technical Fault, and Event logs are stored in non-volatile memory on the Main CPU PCB, ensuring that the information is retained when the ventilator is powered off and during power loss conditions.

To Skip the Welcome Menu Screen:

To skip the Welcome Menu screen, press the **VENTILATION ON/OFF** key to start ventilation immediately.

The Ventilation menu is then displayed, along with a prompt to press the **VENTILATION ON/OFF** key to start ventilation, as shown in the following graphic.



By default, the starting ventilation mode that follows the Welcome menu is the last one used; the settings are those that were active when the machine was last stopped. If the ventilator's memory of the settings is faulty, a "CHECK SETTINGS" alarm is activated. If this occurs, the desired parameters should be reset and re-saved; otherwise the machine will operate on default parameter values.

5.2 Starting Ventilation

Before starting ventilation, refer to Appendix B, "Operational Verification Checklist", and set the parameter values in the Preferences menu.

WARNING

- **Verify the functionality of the main alarms before connecting the patient to the ventilator.**
- **Before starting ventilation, ensure that the device is properly assembled and that the air inlet, cooling vents, and alarm sound diffusion holes are not obstructed. Ensure also that the patient circuit is of the proper configuration (double or single limb), is properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.**
- **You must start the ventilator and allow it to complete one full breath cycle prior to connecting the patient. Do not connect the patient before the first full breath cycle is completed.**

When the ventilator is on standby (the ventilator is on, but ventilation has not started), a message that prompts the ventilator operator to press the **VENTILATION ON/OFF** key to start ventilation is displayed in the right-hand window of the ventilation and alarm menus (Figure 5-3).

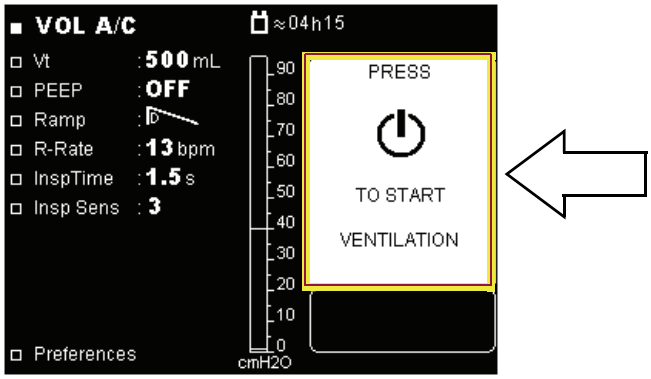


Figure 5-3. Prompt to Start Ventilation

To start ventilation, proceed as follows:

Press and release the **VENTILATION ON/OFF** key (Figure 5-4, item 1).

- The blue light indicator, at the upper right of the **VENTILATION ON/OFF** key (see Figure 5-4, item 2), turns off.
- A “beep“ sounds.
- The ventilation starts.
- The values of the monitored parameters are displayed in the right-hand window.

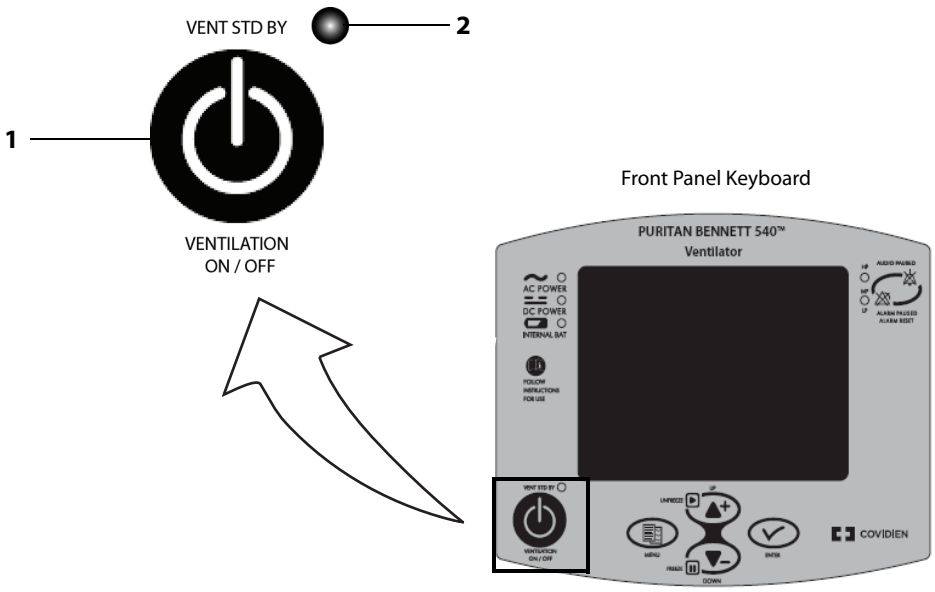


Figure 5-4. Starting Ventilation

5.3 Stopping Ventilation

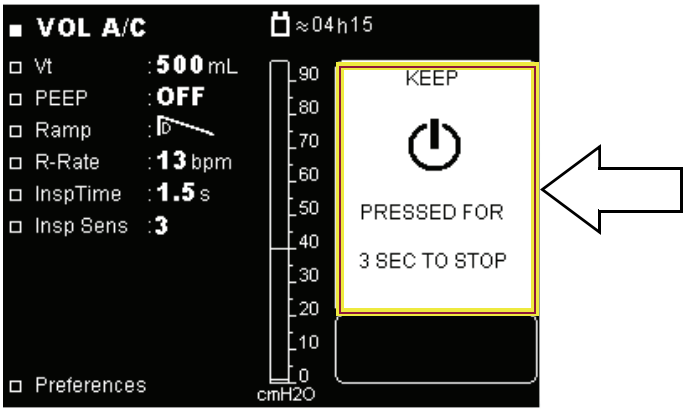
WARNING

Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of expiratory gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

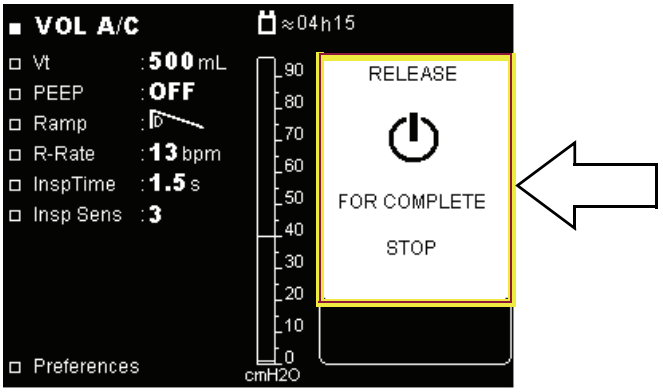
You can stop your ventilator at any time, regardless of which menu is currently displayed.

To stop the ventilator, proceed as follows:

1. Hold down the **VENTILATION ON/OFF** key (Figure 5-4, item 1) for about three (3) seconds.
   - A message prompting the user to keep the button pressed appears on the monitoring window, as shown in the graphic below:



- While keeping the **VENTILATION ON/OFF** key pressed, a new message appears that directs the user to release the key to stop ventilation (shown in the graphic below).



- A double "beep" sounds.

2. Release the **VENTILATION ON/OFF** key:
   - Ventilation stops.
   - The blue LED located to the upper-right of the **VENTILATION ON/OFF** key (Figure 5-4, item 2) illuminates to indicate ventilation is on Standby.
   - A prompt for a new start of ventilation is displayed (see Figure 5-3 on page 5-3).

5.4 Turning Off the Ventilator

WARNING

- **When ventilation is in progress: if the ventilator is stopped using the I/O switch without previously stopping the ventilation, a continuous audible alarm is activated.**
- **When the ventilator is switched back on, it will immediately begin ventilating—without the user first having to press the VENTILATION ON/OFF key.**

Set the **I/O** switch to the **O** position to power off the ventilator.

- The blue LED to the right of the **VENTILATION ON/OFF** key turns off.
- The ventilator screen switches off.

Note:

When the ventilator is completely stopped, but is still connected to the AC power source (the green AC POWER indicator is illuminated), the internal battery continues charging.

WARNING

Handle the ventilator with care after use, particularly when room temperatures are high. Some ventilator surfaces may be very hot, even if safety specifications are not exceeded.

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6 Internal Battery

WARNING

- **Because the internal battery of the Puritan Bennett 540™ Ventilator contains more than 8 grams (equivalent) lithium, it is categorized as Dangerous Goods (DG) Class 9—even though the ventilator meets current safety standards.**
  The ventilator, because of this categorization, is subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA), Internal Maritime Dangerous Goods code for sea, as well as the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe.
  As ADR regulations cover commercial transport only, there are two groups that can be exempted from these regulations. The first group consists of private individuals, providing that the goods are for their own personal use and measures have been taken to prevent leakage. The second group consists of persons that transport the goods because they need the product to execute their job(s). For any other group or purpose, transport must be compliant with Dangerous Goods Regulations. In the case of air transport of the ventilator, whether as checked or carry-on baggage, it is recommended that the users ask the carrier which measures to take prior to transport.
- **Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12– 30 VDC power source (via the DC power cable) does not enable charging of its internal battery.**

6.1 Battery Capacity

The reserve capacity offered by the internal battery depends on the level of adjustments made, the environmental conditions (primarily in terms of temperature), and the physiological characteristics of the patient.

With a fully charged battery at a normal room temperature of 25 ºC (± 5 ºC), the ventilator can be expected to operate on internal battery power for the average durations shown in Table 6-1.

Checking the battery charge level requires that the ventilator be running on battery power at the time of the battery check. To check the battery charge level, temporarily disconnect the ventilator from AC power (while in Stand By mode or while providing ventilation) and read the percent charge level displayed adjacent to the battery icon displayed at the top of the ventilator's display screen.

Table 6-1. Internal Battery Reserve Capacity

Displayed Values	Average Operating Time on Internal Battery Power[a]
Vt = 200 ml (± 5 ml) PIP = 10 cmH_2O (± 2 cmH_2O) Rtot = 20 bpm	11 hours (–10%)
Vt = 300ml (± 5 ml) PIP = 20 cmH_2O (± 2 cmH_2O) Rtot = 15 bpm	9 hours (–10%)
Vt = 500 ml (± 5 ml) PIP = 30 cmH_2O (± 2 cmH_2O) Rtot = 15 bpm	6.5 hours (–10%)
Vt = 750 ml (± 5ml) PIP = 45 cmH_2O (± 2 cmH_2O) Rtot = 20 bpm (Maximum Ventilation Parameters)	4.5 hours (–10%)

a. Average durations shown are with a fully charged battery having less than 50 charge/recharge cycles.

6.2 Battery Operation

Caution

Before operating the ventilator on its internal battery, ensure that the battery is fully charged and that the charge holds (see section 6.4, "Recharging the Battery," on page 6-4).

Note:

Speaker and battery alarms may occur when the unti is first powered on after the internal battery has been completely drained. Connect to an AC power source and recycle power.

In the event of AC power interruption or disconnection of the external AC or DC power supply, the ventilator automatically switches to its internal battery and the following events occur:

- The Battery symbol is displayed at the top on the general information line.
- Battery reserve capacity is displayed on the right of the symbol.
- The "INTERNAL BAT" indicator at the top left of the ventilator's front panel is continuously lit (Figure 6-1).

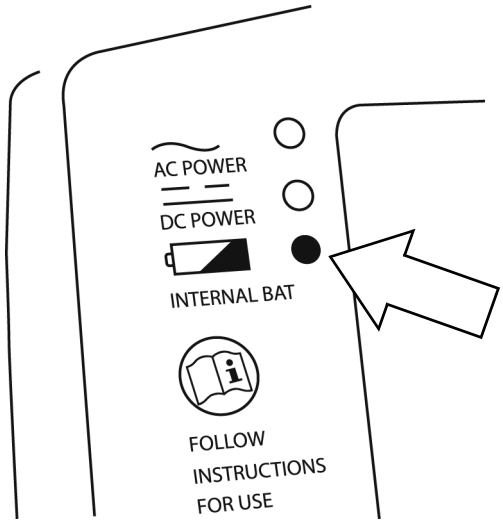
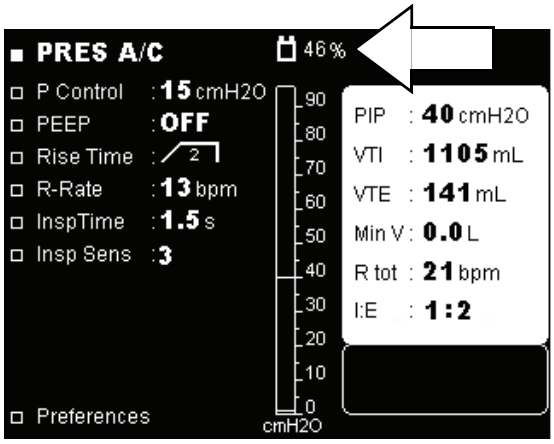


Figure 6-1. Internal Battery Indicator

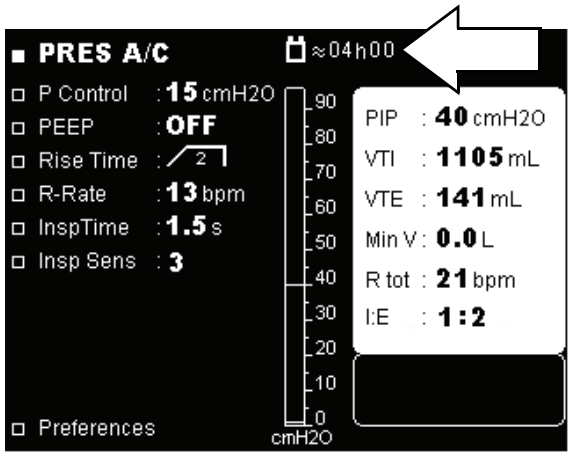
- A loss of external supply alarm is activated.
- A "beep" sounds every five (5) minutes to remind the user that the ventilator is being powered by its internal battery.

If ventilation is *stopped*, the internal battery reserve capacity is displayed as a percentage of battery charge, as shown in the following graphic.



If the ventilator is *running*, the internal battery reserve is momentarily displayed as a percentage. Then, after the ventilator calculates the battery time remaining (which takes about two minutes,

depending on the power consumption of the ventilator), the internal battery reserve is then displayed in hours and minutes (rounded to the nearest fifteen minutes). See the following graphic.



The "LOW BATTERY" and "EMPTY BATTERY" alarms (refer to chapter 3, "Alarms and Troubleshooting") are triggered when the internal battery reserve is reduced.

WARNING

- **Due to its limited internal battery's reserve capacity, the ventilator should only be operated occasionally while powered by its internal battery. Ensure that the internal battery never becomes fully discharged.**
- **When the "LOW BATTERY" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.**

From the time that an "EMPTY BATTERY" alarm is activated, if no external supply is connected to the ventilator, other alarms may be triggered due to insufficient supply voltage.

In the final discharge phase, the "EMPTY BATTERY" alarm will become continuous, and ventilation may be interrupted at any time during this phase.

Note:

The "EMPTY BATTERY" alarm symbol may disappear shortly before the ventilator completely stops, but it always triggers a final, continuous alarm.

6.3 Testing the Battery

Your ventilator continuously and automatically checks the state of the internal battery, even when the battery is not used as the main source of energy. The "BATT FAULT1 CALL SERVICE" alarm is activated whenever a problem is detected in the battery or the charger.

However, on a monthly basis you should disconnect the ventilator from the external power supply to check the integrity of the connections linking the internal battery to other ventilator components.

6.4 Recharging the Battery

In the event that the battery charge level is considered insufficient, as per the reserve capacity display, recharge of the internal battery is necessary. In general, it is recommended that the ventilator be

allowed to charge when it not in use, and that the ventilator be recharged systematically after storage and before using it again.

To charge the internal battery, do the following:

Connect the ventilator to the AC power source.

- The “AC POWER” indicator illuminates (Figure 6-2, item 1).
- The “INTERNAL BAT“ indicator flashes (Figure 6-2, item 2).

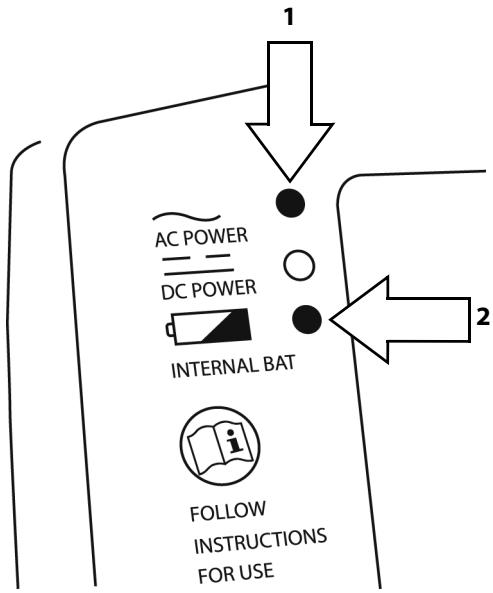


Figure 6-2. Power Indicators When Charging the Battery

When the battery charge is complete, the “INTERNAL BAT“ indicator turns off.

WARNING

Even if the “INTERNAL BAT“ indicator is off, charge of the battery may sometimes be incomplete regardless of charge time when the ambient temperature is above 104 °F (40 °C). This is due to the characteristics of the battery’s internal heat safety device.

Although it is not necessary to start the ventilator to charge the battery, charging the battery during operation will increase the time required to fully charge the internal battery.

When recharging a depleted internal battery, it may be necessary to leave the ventilator on charge for about four (4) hours if the ventilator is on standby and about 10 hours if ventilation is operating.

WARNING

Using the ventilator on an external 12 –30 VDC power source does not enable charging of its internal battery.

6.5 Storing the Battery

If the device is to be stored for an extended period of time, it is not necessary to remove the battery. However, the battery should be stored in cool, dry, well-ventilated environment, as follows:

- Temperature: approximately 70 °F (21 °C)
- Humidity: less than 80% RH

If the battery is stored for more than one month at a temperature greater than 70 °F (21 °C), or for more than one or two weeks at a temperature greater than 113 °F (45 °C), the reserve capacity of the battery may be affected. It will then be necessary to recharge the battery before using it again.

The battery should not be stored for more than two years, whatever the conditions.

6.6 Replacing the Battery

⚠ **WARNING**

- The ventilator must be disconnected from all external power supplies and be turned off during this operation.
- Batteries should be disposed of according to environmental legislation in your country and locality.
- Never expose any batteries to direct flame.
- Never touch the ventilator's internal components, including the battery, and the patient simultaneously.

To replace the Battery, refer to Figure 6-3 and proceed as follows:

1. Place the ventilator on a work table.
2. Remove the three (3) screws (Figure 6-3, item 1) securing the battery cover with a **"**Torx**"** T10 screwdriver. These screws consist of two (2) Torx head screws on the rear panel and one (1) Torx head screw on the bottom of the ventilator, as shown—depending on the version of the device.

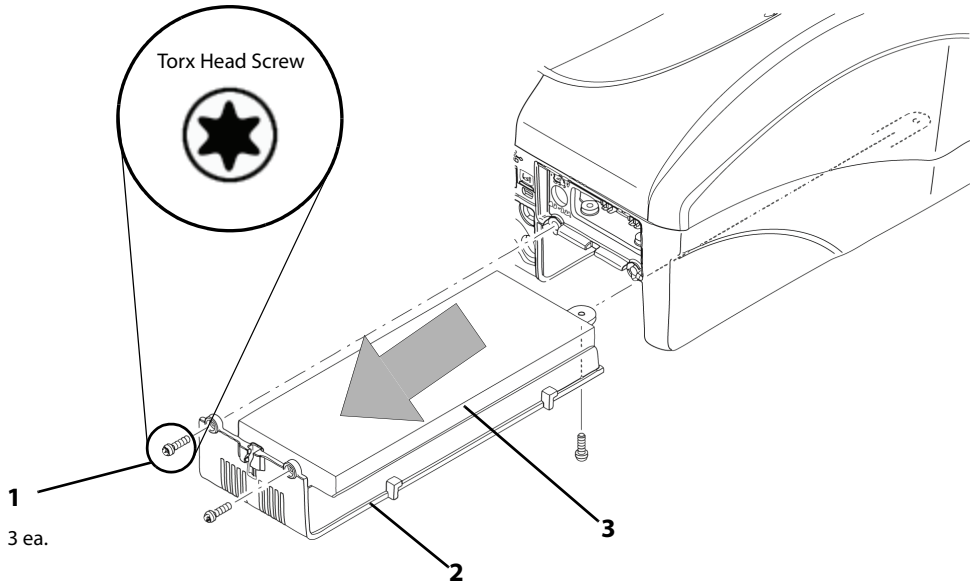


Figure 6-3. Replacing the Battery

3. Slide the battery cover (Figure 6-3, item 2) off by pulling it towards the back of the ventilator.
4. Remove the old battery (Figure 6-3, item 3) from the battery cover.
5. Remove the replacement battery from its package and install it into the battery cover. Ensure that:
   - You remove the protective "pull tabs" (if they are present) from the battery's contacts.
   - The battery's contacts align with those of the ventilator, according to the drawing on the label on the back of the battery cover.

6. Place the battery cover containing the replacement battery back onto its slide rails within the ventilator.

Caution

When tightening the screws in the next step, push on the battery cover from the rear towards the front to take pressure off the cover mounting brackets; otherwise, the cover mounting brackets may break when the screws are tightened.

7. Install the three Torx screws (Figure 6-3, item 1) to secure the battery cover (Figure 6-3, item 2) to the ventilator and tighten the screws with the Torx T10 screwdriver.

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7 Cleaning

WARNING

- **A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is recommended.**
- **To reduce the risk of infection, be sure to wash your hands thoroughly before and after handling the ventilator or its accessories.**

7.1 Cleaning the Ventilator

Clean all external panels and surfaces before and after each patient use and as often as necessary to keep the ventilator clean. You should clean the ventilator periodically, whenever it is soiled or dirty, before any maintenance operation, and before storing the ventilator.

WARNING

- **Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in Table 7-1.**
- **Fluids must not be allowed to enter the device, particularly through the air inlet filter or the cooling apertures located in the side, rear, and bottom panels of the ventilator.**
- **The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.**

To clean the surface of the ventilator, do the following:

1. Dip a clean, soft cloth into a mixture of mild soap and water, or other approved cleaning solution. Refer to Table 7-1 for a list of approved cleaning solutions.
2. Squeeze the cloth thoroughly to remove excess liquid.
3. Lightly wipe the external casing of the ventilator, taking care not to allow excess moisture to enter any of the openings on the ventilator's surface. See the warning, above.
4. Dry the ventilator surface with a clean, soft, lint-free cloth.

Table 7-1. Approved Cleaning Solutions for Exterior Ventilator Surfaces

Description	Product Names
Tap water	–
Saline	–
Mild dishwashing detergent	Joy® (or equivalent)
70% isopropyl alcohol (rubbing alcohol)	–
10% chlorine bleach (90% tap water)	Clorox® (or equivalent)

Table 7-1. Approved Cleaning Solutions for Exterior Ventilator Surfaces (Continued)

Description	Product Names
Glutaraldehyde	Cidex® (or equivalent)
Hospital disinfectants	• Professional Amphyl® • Cavicide® • Control III®
Hydrogen peroxide	–
15% ammonia (85% tap water)	–
Ammonia-based household cleaners	Windex®
Household cleaners	Formula 409®

7.2 Cleaning the Accessories

Follow the accessory manufacturer's instructions for cleaning the ventilator's accessories and components, including the patient circuit.

⚠ **WARNING**

After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.

Caution

Never use a liquid cleaner inside the patient circuit, or on any component of a gas or air pathway.

8 Routine Maintenance

WARNING

- **On a DAILY basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.**
- **Do not attempt to repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only qualified service personnel should repair or service the ventilator.**

8.1 Replacing the Air Inlet Filter

WARNING

- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. Replace it when necessary—even before the recommended replacement period has elapsed, and particularly when the ventilator is installed on the wheelchair. Environmental conditions may cause the filter to become dirty more rapidly.**

Caution

- Failing to replace a dirty filter or operating the ventilator without a filter, may cause serious damage to the ventilator.
- The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.

If the ventilator is used indoors, the condition of the air inlet filter should be checked monthly. If the ventilator is used outdoors or in a dusty environment, the air inlet filter should be checked weekly and replaced as necessary.

To replace the air inlet filter, proceed as follows:

1. Hold the filter between your fingers (see Figure 8-1, item 1).
2. Remove the filter (Figure 8-1, item 2) and discard it.
3. Place the new filter in the device, while ensuring that:
   a. The fine particle side of the filter faces *outwards*, away from the ventilator.
   b. The filter is properly installed in its housing. Proper installation of the filter prevents particles from entering the device.

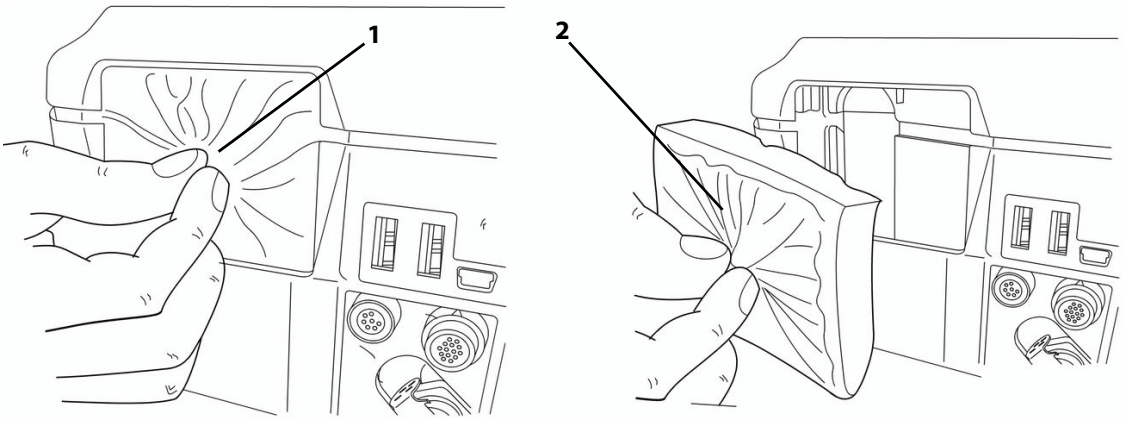

Figure 8-1. Replacing the Air Inlet Filter

8.2 Recommended Schedule of Maintenance

Consumables and Replacement Intervals

When used under normal circumstances—a relatively dust-free atmosphere, and without damage to the device and its components (shocks, cracks, significant dirt, and so on)—the intervals for replacing the ventilator's consumable elements are as follows:

Table 8-1. Consumables and Replacement Intervals

Elements	Recommended Replacement Intervals
Air Inlet Filter (Foam + Fine Particle)	Every two months or more often, depending on the extent of soiling
Inspiratory Bacteria Filter	See manufacturer's recommendation
Patient Circuit	See manufacturer's recommendation
Exhalation Block	3 months (for each new patient)

Note:

For more information regarding parts and accessories for the Puritan Bennett 540 Ventilator contact your service representative or www.puritanbennett.com.

⚠ **WARNING**

- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. Replace it when necessary—even before the recommended replacement period has elapsed, and particularly when the ventilator is installed on the wheelchair. Environmental conditions may cause the filter to become dirty more rapidly.**

Failure to observe these recommendations may result in a loss of performance, excessive overheating, a loss of certain functions and, in the long term, compromise the longevity of the ventilator.

Maintenance of the Internal Battery

The internal battery does not need to be removed to verify its correct operation.

Periodic Test of the Internal Battery

Your ventilator continuously and automatically checks the state of the internal battery, even when the internal battery is not used as the main power source.

However, the battery charge status should be checked MONTHLY by disconnecting the ventilator from external power supplies (refer to section 6.2, "Battery Operation"). Such a test is *imperative* after opening the ventilator or after a prolonged period of non-use (one month or more), in order to ensure the correct operation of internal connections linking the battery to other components.

Caution

Do not store the internal battery, either installed within or removed from the ventilator, for more than two (2) years. Storage here is taken to mean a period of continuous non-use.

Replacement of the Internal Battery

The internal battery should be replaced when the battery capacity drops below 3450 mAh. Keep in mind that, for environmental protection, the ventilator and its components—including its internal battery—cannot be disposed of with household waste. You must submit the ventilator and its components for suitable selective collection and possible recycling and observe all applicable regulations.

Note: As the total number of battery charge/discharge cycles approaches 300, a drop in potential of as much as 20% may be detected.

8.3 Service Assistance

WARNING

- **If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.**
- **Do not attempt to repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only qualified service personnel should repair or service the ventilator.**

In the event of a problem with the ventilator, refer to chapter 3, "Alarms and Troubleshooting". If you cannot determine the cause of the problem, contact your equipment supplier or Puritan Bennett.

Corporate Address:

Covidien
6135 Gunbarrel Avenue
Boulder, CO 80301
U.S.A.

Technical Service Phone Numbers:

Troubleshooting your portable ventilator: 1-800-255-6774
Servicing your portable ventilator: 1-800-255-6774

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A Specifications

A.1 Physical

Table A-1. Physical Description (Excluding Accessories)

Ventilator Weight	9.9 lb. (4.5 kg)
Ventilator Dimensions	9.25 in wide x 12.40 in deep x 6.0 in high (235 mm wide x 315 mm deep x 154 mm high)
Connectors	Inspiratory limb connector: ISO 22 mm (OD) conical Expiratory limb connector (on expiratory block): ISO 22 mm (ID) conical Oxygen inlet: Female Connector with valve
Device airway volume	2000 ml
Breathing circuit volume	
• Adult, dual limb	1150 ml
• Pediatric, dual limb	670 ml
• Adult, single limb	550 ml
• Pediatric, single limb	300 ml
Air Inlet Filter	Dimensions: 70 mm long x 60 mm wide Composition: Polypropylene fiber electrostatic filter material, which is laminated onto polyurethane open-celled foam. Efficiency: 99.54% at 24 lpm(filtering microbes 2.5 µm to 3 µm)
Inspiratory Bacteria Filter Requirement	Maximum allowable flow resistance: 4cmH2O at 60 lpm

A.2 Electrical

Table A-2. AC Electrical Supply

Voltage	Frequency	Consumption
100 VAC to 240 VAC	50 Hz / 60 Hz	180 VA max.
12 VDC	NA	8.3 A
30 VDC	NA	3.3 A

Table A-3. Internal Lithium Ion Battery

Voltage	25.2 VDC
Full-load capacity	4.8 Ah
Ampere-hour rating	On standby: 1.5 Ah
	During ventilation: 0.5 Ah
Charging current • Standby mode • Ventilation mode	 1.5 A/hr. (duration: < 6 hr.) 0.5 A/hr. (duration: < 13 hr.)
Average operating time at 25 °C (± 5 °C) with a fully charged battery (having less than 50 charge/discharge cycles) at the following displayed values:	
Vt = 200 ml (± 5 ml), PIP = 10 cmH_2O (± 2 cmH_2O), Rtot = 20 bpm	11 hr. (–10%)
Vt = 300 ml (± 5 ml), PIP = 20 cmH_2O (± 2 cmH_2O), Rtot = 15 bpm	9 hr. (–10%)
Vt = 500 ml (± 5 ml), PIP = 30 cmH_2O (± 2 cmH_2O), Rtot = 15 bpm	6.5 hr. (–10%)
Vt = 750 ml (± 5 ml), PIP = 45 cmH_2O (± 2 cmH_2O), Rtot = 20 bpm	4.5 hr. (–10%)
(maximum settings)	

Table A-4. Remote Alarm

Remote Alarm Port:

Also known as the Nurse's Call port, it provides for remote alerts of ventilator alarm conditions.

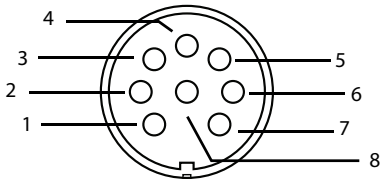
An example of a setting that requires such a feature is when the ventilator is used in an isolation room.

The ventilator signals an alarm using a normally open (NO) or a normally closed (NC) signal.

A remote alarm is activated when an alarm condition occurs, unless either of the following is true:

- Audio paused function is active
- Ventilator power switch is turned off

The remote alarm port is an 8-pin female connector. Allowable current is 100 mA at 24 VDC (maximum).



Nurse call pin-out (view from back of ventilator)

Pin	Signal	Wire color
1	relay common	black
2	normally closed (NC)	orange
3	normally open (NO)	brown
4	remote supply -(not used)	-
5	RX Signal (not used)	-
6	TX Signal (not used)	-
7	remote supply +(not used)	-
8	not used	-

A.3 Indicators and Alarms

Table A-5. Power Indicators

Ventilation ON/OFF	AC power	DC power	INTERNAL BAT
• Blue in standby mode • Not lit if ventilation is in progress.	Green	Green	• Flashing if the battery charge is in progress. • Continuously lit if the ventilator is powered by the internal battery.

Table A-6. Alarm Indicators

High Priority	Medium Priority
Red flashing LED	Yellow flashing LED

Table A-7. Audio Alarms

Audio Paused	Alarm Volume
60 s ± 1 s	65 to 85 dBA ± 10% at 1 meter

A.4 Performance

A.4.1 Specifications

Table A-8. Performance Parameter Specifications and Tolerances

Settings	Range	Tolerances
Volume	50 to 2000 ml	± (10 ml + 10%)
Pressure	5 to 55 cmH_2O	± (1 cmH_2O ± 10%)
Time	0.3 to 6.0 s	± 10%
Rate	1 to 60 bpm	± 1 bpm
Inspiratory Sensitivity	1P to 5	N/A
Exhalation Sensitivity	5 to 95%	N/A

A.4.2 Test Results

Table A-9. Volume Performance Test Results

R-Rate (bpm)		**5**	**10**	**15**	**20**	**30**	**40**	**50**	**60**
Insp Time(s)		**4.0**	**2.0**	**1.3**	**1.0**	**0.7**	**0.5**	**0.4**	**0.3**
C50 R5	VTI min. (ml)	220	110	80	60	60	NA	NA	NA
	VTI max. (ml)	2000	2000	1750	1200	700	NA	NA	NA
C20 R20	VTI min. (ml)	NA	110	80	60	60	NA	NA	NA
	VTI max. (ml)	NA	1000	900	700	400	NA	NA	NA
C20 R20	VTI min. (ml)						NA	NA	NA
	VTI max. (ml)						NA	NA	NA

Table A-9. Volume Performance Test Results

R-Rate (bpm)		**5**	**10**	**15**	**20**	**30**	**40**	**50**	**60**
Insp Time(s)		**4.0**	**2.0**	**1.3**	**1.0**	**0.7**	**0.5**	**0.4**	**0.3**
C10 R50	VTI min. (ml)	NA	NA	80	60	60	60	NA	NA
	VTI max. (ml)	NA	NA	400	350	250	90	NA	NA
C3 R50	VTI min. (ml)	NA	NA	NA	60	60	60	60	NA
	VTI max. (ml)	NA	NA	NA	170	140	90	70	NA

Note: "NA" in Table A-9 indicates data not applicable to the patient groups tested (represented by designators "C" and "R").

A.5 Monitored Parameters

Table A-10. Monitored Parameter Specifications and Tolerances

Ventilator Parameters	**Range**	**Tolerances**
Peak Inspiratory Pressure (PIP)	0 to 140 cmH_2O	± (0.2 cmH_2O + 8%)
Positive End Expiratory Pressure (PEEP)[a]	0 to 99 cmH_2O	± (0.2 cmH_2O + 8%)
Inspiratory Tidal Volume (VTI)	0 to 9995 ml	± (10 ml + 10%VTI)*Rate
Expiratory Tidal Volume (VTE)	0 to 9995 ml	± (10 ml + 10%VTE)*VTE
Total Breath Rate (Rtot)	0 to 99 bpm	± 1 bpm
Mean Airway Pressure (MAP)	0 to 99 cmH_2O	± (0.4 cmH_2O + 8%)
I:E Ratio (I:E)	9.9:1 to 1:9.9	± 50 ms or 10%, whichever is greater
Inspiratory Time (I Time)	0 to 59.9 s	± 50 ms or 10%, whichever is greater
Expiratory Time (E Time)	0 to 59.9 s	± 50 ms or 10%, whichever is greater
Inspiratory Minute Volume (Min VI)	0 to 99.9 l	+/- (10ml + 10%)
Expiratory Minute Volume (Min VE)	0 to 99.9 l	+/- (20ml + 20%) in CPAP mode above 200ml

a. The PB 540 does not have the capability to reduce pressure below the PEEP pressure during the expiratory phase.

A.6 Range, Resolution, and Accuracy

Table A-11 lists the ranges, resolutions, and accuracies for ventilator settings, alarm settings, and patient data.

Table A-11. Ventilator Range, Resolution, and Accuracy

Setting or Monitored Parameter	Range, Resolution, and Accuracy
Ventilator Settings	
Tidal volume (Vt)	Range: 50 mL to 2000 mL Resolution: 10 mL Accuracy: ± (10 ml + 10%) of setting Default value: 500 mL Depends on: Insp time, R-Rate
Pressure control (P Control)	Range: 5 cmH_2O to 55 cmH_20 Resolution: 1 cmH_2O Accuracy: ± (1 cmH_2O + 10%) of P Control + PEEP setting Default value: 15 cmH_2O
Pressure support (P Support)	Range: OFF or 5 cmH_2O to 55 cmH_20 Resolution: 1 cmH_2O Accuracy: ± (1 cmH_2O + 10%) of P Support + PEEP setting Default value: 15 cmH_2O
Inspiratory time (Insp Time)	Range: 0.3 s to 6.0 s for VOL A/C and PRES A/C 0.3 s to 4.0 s for V SIMV and P SIMV Resolution: 0.1 s Accuracy: ± 10% Default value: 1.5 s Depends on: R-Rate, Vt
Respiratory rate (R-Rate)	Range: 5 bpm to 60 bpm in VOL A/C and PRES A/C modes 1 bpm to 40 bpm in P SIMV and V SIMV modes Resolution: 1 bpm Accuracy: ± 1 bpm Default value: 13 Depends on: High Rtot, Insp Time, Vt
Inspiratory sensitivity (Insp Sens)	Range: 1P-5 Resolution: 1 Accuracy: NA Default value: 2
Exhalation sensitivity (Exh Sens)	Range: 5% to 95% of peak flow Resolution: 5% Accuracy: +/- (4 lpm +10%) of target exhalation flow based on Exh Sense Default value: 25% In CPAP, V SIMV, and P SIMV, Exh Sens is fixed at 25% and is not adjustable.
Ventilator Settings (Cont'd)	

Table A-11. Ventilator Range, Resolution, and Accuracy (Continued)

Setting or Monitored Parameter	Range, Resolution, and Accuracy
Mode	Range: VOL A/C, PRES A/C, V SIMV, P SIMV, PSV/CPAP Resolution: N/A Accuracy: N/A Default value: PRES A/C
Flow Pattern (flow pattern)	Range: Square, descending ramp Resolution: N/A cmH_2O Default value: Square, descending ramp In V SIMV, flow pattern is set to square and is not adjustable
PEEP	Range: OFF (0.5 cmH_2O) to 20 cmH_2O Resolution: 1 cmH_2O Accuracy: ± (1 cm H_2O + 10%) cmH_2O Default value: OFF
Rise time	Range: 1-4 Resolution: 1 Default value: 2 Depends on: Insp time In P SIMV and V SIMV, rise time is set to 2 and is not adjustable.
Backup rate	Range: 5-40 bpm Resolution: 1 bpm Default value: 13 Depends on: Min Insp. time In P SIMV and V SIMV, Backup rate = Max (8, R-Rate)
Apnea time	Range: AUTO or 1-60 s Resolution: 1 s Default value: AUTO Depends on: Backup R In PSV, Apnea time: AUTO = 60/Backup R s, or Apnea time: AUTO = 30 s In V SIMV or P SIMV, Apnea Time: AUTO = 12
Alarm settings (based on breath mode)	
Pressure A/C Mode	
Low Inspired Tidal Volume (Low VTI)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: 300 Depends on: High VTI
High Inspired Tidal Volume (High VTI)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 2000 mL Depends on: Low VTI
Pressure A/C Mode (Cont'd)	

Table A-11. Ventilator Range, Resolution, and Accuracy (Continued)

Setting or Monitored Parameter	Range, Resolution, and Accuracy
Low Exhaled Tidal Volume (Low VTE)	Range: 30 mL to 1990 mL Resolution: 10 mL Default value: 300 Depends on: High VTE
High Exhaled Tidal Volume (High VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 1000 Depends on: Low VTE
Low Minute Volume (Low Min Vol)	Range: 0.5 L to 50.0 L Resolution: 0.1 L Default value: 4.0 Depends on: High Min vol
High Minute Volume (High Min Vol)	Range: 2.0 L to 99.0 L Resolution: 0.1 L Default value: 13 Depends on: Low Min vol
High Respiratory Rate (High Rtot)	Range: 10 bpm to 70 bpm Resolution: 1 bpm Default value: OFF Depends on: R-Rate
Low Peak Inspiratory Pressure (Low PIP)	Range: PIP- 20% (not adjustable) Resolution: N/A
High Peak Inspiratory Pressure (High PIP)	Range: PIP+ 20% (not adjustable) Resolution: N/A
PSV/CPAP Mode	
Low inspired tidal volume (Low VTI)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: OFF Depends on: High VTI
High inspired tidal volume (High VTI)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 2000 mL Depends on: Low VTI
Low exhaled tidal volume (Low VTE)	Range: 30 mL to 2000 mL Resolution: 10 mL Default value: OFF Depends on: High VTE
High exhaled tidal volume (High VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: OFF Depends on: Low VTE
PSV/CPAP Mode (Cont'd)	

Table A-11. Ventilator Range, Resolution, and Accuracy (Continued)

Setting or Monitored Parameter	Range, Resolution, and Accuracy
Low Minute Volume (Low Min Vol)	Range: 0.5 L to 50.0 L Resolution: 0.5 L Default value: OFF Depends on: High Min vol, VTI, R-Rate
High Minute Volume (High Min Vol)	Range: 2.0 L to 99.0 L Resolution: 0.5 L Default value: OFF Depends on: Low Min vol, VTI, R-Rate
High respiratory rate (High Rtot)	Range: 10 bpm to 70 bpm Resolution: 1 bpm Default value: OFF Depends on: Backup R
Minimum inspiratory time (Low I time)	Range: 0.1 to 3s Resolution: 0.1 s Default value: AUTO (Rise time + 300 ms) Depends on: High I time, Backup R, Rise time
Maximum inspiratory time (High I time)	Range: 0.8 to 3 s Resolution: 0.1 s Default value: AUTO {Min [3 s; (30/R-Rate)]} Depends on: Low I time, R-Rate
Low Peak Inspiratory Pressure (Low PIP)	Range: PIP – 20% (not adjustable) Resolution: N/A
High Peak Inspiratory Pressure (High PIP)	Range: PIP + 20% (not adjustable) Resolution: N/A
V SIMV Mode	
Low PIP	Range: 2 cmH_2O to 52 cmH_2O Resolution: 1 cmH_2O Default value: 2 cmH_2O Depends on: PEEP, P support, High PIP
High PIP	Range: 12 cmH_2O to 60 cmH_2O Resolution: 1 cmH_2O Default value: 40 cmH_2O Depends on: PEEP, P support, Low PIP
Low Inspired Tidal Volume (Low VTI)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: OFF Depends on: Vt, High VTI
High Inspired Tidal Volume (High VTI)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 2000 mL Depends on: Vt, Low VTI
V SIMV Mode (Cont'd)	

Table A-11. Ventilator Range, Resolution, and Accuracy (Continued)

Setting or Monitored Parameter	Range, Resolution, and Accuracy
Low Exhaled Tidal Volume (Low VTE)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: OFF Depends on: Vt, High VTE
High Exhaled Tidal Volume (High VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: OFF Depends on: Vt, Low VTE
Low Minute Volume (Low min. vol)	Range: 0.5 L to 50 L Resolution: 0.5 L Default value: OFF Depends on: Vt, R-Rate, High Min vol
High Minute Volume (High min. vol)	Range: 2 L to 99 L Resolution: 0.5 L Default value: OFF Depends on: Vt, R-Rate, Low Min vol
High Respiratory Rate (High Rtot)	Range: 10 bpm to 70 bpm Resolution: 1 bpm Default value: OFF Depends on: R-Rate
Minimum inspiratory time (Low I time)	Range: RISE TIME + 300ms (not adjustable)
Maximum inspiratory time (High I time)	Range: Min [3s; (30/R-Rate)] (not adjustable)
P SIMV Mode	
Low Inspired Tidal Volume (Low VTI)	Range: 30 mL to 2000 mL Resolution: 10 mL Default value: OFF Depends on: High VTI
High Inspired Tidal Volume (High VTI)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 2000 mL Depends on: Low VTI
Low Exhaled Tidal Volume (Low VTE)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: OFF Depends on: High VTE
High Exhaled Tidal Volume (High VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: OFF Depends on: Low VTE
P SIMV Mode (Cont'd)	

Table A-11. Ventilator Range, Resolution, and Accuracy (Continued)

Setting or Monitored Parameter	Range, Resolution, and Accuracy
Low Minute Volume (Low Min Vol)	Range: 0.5 L to 50 L Resolution: 0.5 L Default value: OFF Depends on: High Min vol
High Minute Volume (High Min Vol)	Range: 2 L to 99 L Resolution: 0.5 L Default value: OFF Depends on: Low Min vol
High Respiratory Rate (High Rtot)	Range: 10 bpm to 70 bpm Resolution: 1 bpm Default value: OFF Depends on: R-Rate
Low Peak Inspiratory Pressure (Low PIP)	Range: PIP- 20% (not adjustable) Resolution: N/A
High Peak Inspiratory Pressure (High PIP)	Range: PIP+ 20% (not adjustable) Resolution: N/A
Minimum Inspiratory time (Low I time)	Range: RISE TIME + 300ms (not adjustable)
Maximum Inspiratory time (High I time)	Range: Min [3s; (30/R-Rate)] (not adjustable)
Volume A/C Mode	
Low PIP	Range: 2 cmH_2O to 52 cmH_2O Resolution: 1 cmH_2O Default value: 2 cmH_2O Depends on: PEEP, High PIP
High PIP	Range: 12 cmH_2O to 60 cmH_2O Resolution: 1 cmH_2O Default value: 40 cmH_2O Depends on: PEEP, Low PIP
Low Exhaled Tidal Volume (Low VTE)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: OFF Depends on: Vt, High VTE
High Exhaled Tidal Volume (High VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: OFF Depends on: Vt, Low VTE
Low Minute Volume (Low Min Vol)	Range: 0.5 L to 50 L Resolution: 0.5 L Default value: OFF Depends on: Vt, R-Rate, High Min vol

Table A-11. Ventilator Range, Resolution, and Accuracy (Continued)

Setting or Monitored Parameter	Range, Resolution, and Accuracy
High Minute Volume (High Min Vol)	Range: 2 L to 99 L Resolution: 0.5 L Default value: OFF Depends on: Vt, R-Rate, Low Min vol
High Respiratory Rate (High Rtot)	Range: 10 bpm to 70 bpm Resolution: 1 bpm Default value: OFF Depends on: R-Rate
Monitored Patient Data	
Peak inspiratory pressure (PIP)	Range: 0 cmH_2O to 99 cmH_2O Resolution: 1 cmH_2O Accuracy: ± (0.2 cmH_2O+ 8%)
Positive end expiratory pressure (PEEP)	Range: 0 cmH_2O to 99 cmH_2O Resolution: 1 cmH_2O Accuracy: ± (0.2 cmH_2O + 8%)
Inspiratory tidal volume (VTI)	Range: 0 mL to 9,995 mL Resolution: 5 mL Accuracy: ± (10ml + 10%)
Expiratory tidal volume (VTE)	Range: 50 mL to 9,995 mL Resolution: 5 mL Accuracy: ± (10ml + 10%) for volumes ≥ 50ml A "—" symbol is displayed for volumes below 50ml
Inspiratory minute volume (Min VI)	Range: 0 L to 99.9 L Resolution: 0.1 L Accuracy: ± 20%
Expiratory minute volume (Min VE)	Range: 0 L to 99.9 L Resolution: 0.1 L Accuracy: ± 20%
Total respiratory rate (R tot)	Range: 0 bpm to 99 bpm Resolution: 1 bpm Accuracy: ± 1 bpm
Mean airway pressure (MAP)	Range: 0 cmH_2O to 99 cmH_2O Resolution: 1 Accuracy: +/- (0.2 cmH2O + 8%)
I:E ratio (I:E)	Range: 9.9:1 to 1:9.9 Resolution: 0.1 Accuracy: ± (50ms or 10% whichever is greater)
Inspiratory time (I time)	Range: 0 s to 59.9 s Resolution: 0.1 s Accuracy: ± 50 ms or 5%, whichever is greater
Expiratory time (E time)	Range: 0 s to 59.9 s Resolution: 0.1 s Accuracy: ± 50 ms or 10%, whichever is greater

A.7 Environmental

The following environmental conditions shall be observed:

Table A-12. Environmental Conditions for Storage or Transport

Temperature	Humidity-40 °F to 158 °F (-40° C to +70° C)	Atmospheric pressure	Altitude
-40 °F to +158 °F (-40° C to +70° C)	10% to 95% RH	7.2 psi to 15.4 psi (50 kPa to 106 kPa)	-500ft to 13,000 ft (-152 m to 3964 m)

Table A-13. Environmental Conditions for Operation

Temperature	Humidity	Atmospheric pressure	Altitude
+41 °F to10 4 °F (+5°C to 40°C)	10% to 95% RH	8.7 psi to 16.0 psi (60 kPa to 110 kPa)	-500ft to 13,000 ft (-152 m to 3964 m)

Under extreme conditions of use that are beyond the recommendations above but within the limits of a supply voltage of –20%, compared to the nominal temperature or the combination of a temperature of 113 °F (45 °C) and humidity of 75% HR, the ventilator should not malfunction nor endanger the user. However, operating the device for prolonged periods or repeatedly under such extreme conditions could result in premature aging of components and more frequent maintenance.

A.8 Pneumatic

Table A-14. Airway Resistances

Inspiratory	Expiratory
1.0 cmH_2O at 30 lpm flow	0.5 cmH_2O at 30 lpm
3.7 cmH_2O at 60 lpm flow	1.1 cmH_2O at 60 lpm

Table A-15. Patient Circuit Resistances[a]

Adult Double Limb	Pediatric Double Limb
≤ 2 cmH_2O at 60 lpm flow[b]	≤ 2 cmH_2O at 30 lpm flow

a. Includes exhalation valve
b. Values obtained from the manufacturer's (DAR) directions for use.

Table A-16. Air Inlet Resistance (Filter)

0.057 cmH_2O (5.6 pascals)[a] at 24 lpm flow

a. All testing conducted on 3-inch diameter test piece

Table A-17. Oxygen Inlet Specifications

Maximum pressure	Maximum flow
7.25 psi (50 kPa)	15 lpm

Table A-18. Performance Specifications

Working pressure	Sound pressure level	Maximum pressure limit	Internal compliance (ventilator)	Inspiratory triggering response time (Ttr)
5 cmH_2O – 55 cmH_2O	30 dBA (per NF EN ISO 17510-1 test conditions)	61.2 cmH2O (60 mbar)	.0001 l/cmH_2O	100 ms

A.9 Manufacturer's Declaration

The following tables, Table A-19 through Table A-23, contain the manufacturer's declarations for the ventilator's electromagnetic emissions, electromagnetic immunity, and recommended separation distances between the ventilator and portable and mobile RF communications equipment, as well as a list of compliant cables.

⚠ **WARNING**

- **Portable and mobile RF communications equipment can affect the performance of the Puritan Bennett 540™. Install and use this device according to the information contained in this manual.**
- **The ventilator should not be used adjacent to or stacked with other equipment, except as specified in this manual. If adjacent or stacked use is necessary, the ventilator should be observed to verify normal operation in the configurations in which it will be used.**

Table A-19. Electromagnetic Emissions

The Puritan Bennett 540™ Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	The ventilator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ventilator is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table A-20. Electromagnetic Immunity

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment–Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	AC power ("mains") quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV lines/lines ± 2 kV lines/earth	± 1 kV lines/lines ± 2 kV lines/earth	AC power ("mains") power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	AC power ("mains") power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Table A-21. Electromagnetic Immunity – Conducted and Radiated RF

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment–Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms inside ISM bands[a]	3 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms inside ISM bands	$d = 0.35\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	20 V/m (per Draft Reviewer Guidance for Ventilators, July 1995) 80 MHz to 1.0 GHz 10V/m 1.0 GHz to 2.5 GHz	20 V/m (per Draft Reviewer Guidance for Ventilators, July 1995) 80 MHz to 1.0 GHz 10V/m 1.0 GHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol:

Table A-21. Electromagnetic Immunity – Conducted and Radiated RF (Continued)

Note:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz'; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the Legendair XL2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Puritan Bennett 540™.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table A-22. Recommended Separation Distances

The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter**			
	150 kHz to 80 MHz (outside ISM bands) $d = 0.35\sqrt{P}$	**150 kHz to 80 MHz** (in ISM bands) $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.035 m	0.12 m	0.12 m	0.23 m
0.1	0.11 m	0.38 m	0.38 m	0.73 m
1	.35 m	1.2 m	1.2 m	2.3 m
10	1.1 m	3.8 m	3.8 m	7.3 m
100	3.5 m	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table A-23. Compliant Cables and Accessories

Cable or Accessory	**Maximum length**
AC power cable, North America (part no. 2971999)	5.9 ft (1.8 m)
Nurse call cable (part no. 3829800)	16.4 ft (5 m)
12V DC cables (3824600)	TBD

⚠ WARNING

The use of accessories and cables other than those specified, with the exception of parts sold by Puritan Bennett as replacements for internal components, may result in increased emissions or decreased immunity of the ventilator.

A.10 Standards Compliance and IEC Classification

General Standards

- Medical Electrical Equipment: General Requirements for Safety IEC60601-1 1990 and all its amends up to 1996.
- The ventilator will be constructed to comply with the following product Classifications as detailed in Clause 5 of 60601-1:
  - Class II Equipment
  - Internally Powered Equipment
  - Type BF Applied Parts
  - IP31 with respect with respect to access to hazardous parts and ingress of moisture
  - Not suitable for use in the presence of flammable anesthetic mixtures
  - Not suitable for sterilization
  - Suitable for continuous operation
  - Detachable power supply cord
- Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment - Part 1: General Requirements for Safety.
- UL 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety June 30, 2003.

Collateral Standards

- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard Electro-Magnetic Compatibility requirements and tests IEC 60601-1-2 2007.
- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Programmable Electrical Medical Systems IEC 60601-1-4 2000.
- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Usability IEC 60601-1-6 2006.
- General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8 2004.

Particular Standards

- Lung Ventilators for Medical Use- Particular Requirements for Basic Safety and Essential Performance Part 2: Home Care Ventilators for Ventilator-Dependent Patient ISO10651-2 2004.
- Standard Specification for Ventilators Intended for Use in Critical Care ASTM F 1100 1997.

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B Operational Verification Checklist

The operational verification and safety checks listed in Table B-1 below should be performed to ensure the ventilator is operating properly in the following circumstances:

- Prior to using the ventilator with a patient
- Monthly while the ventilator is in use
- Following maintenance or changes in ventilator settings

If the ventilator fails any of the safety checks below, or if you cannot complete these checks, refer to section 3.8, "Troubleshooting," on page 3-14 or call the equipment supplier or Puritan Bennett.

WARNING

- **Provide the patient with an alternate means of ventilation before conducting these tests.**
- **To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.**

Table B-1. Operational Verification Checklist

1	Verify the proper appearance and cleanliness of the ventilator.	☐ Pass
2	Verify all of the labels and markings on the ventilator are clear and legible.	☐ Pass
3	Confirm the air inlet filter is clean and correctly installed.	☐ Pass
4	Ensure the AC power cable does not exhibit any signs of damage, such as kinks, breaks, or damaged insulation.	☐ Pass
5	Connect the AC power cable. Ensure that all power supply indicators on the front panel flash, except for the AC power supply (mains) indicator, which should remain lit.	☐ Pass
6	Push the power switch **I/O** to the **I** position to activate the ventilator test: Check that the two alarm indicators and the Standby indicator (located close to the **VENTILATOR ON/OFF** key) flash. Ensure also that the two alarm buzzers sound.	☐ Pass
7	Perform the Functioning Alarms Test.	☐ Pass
8	Verify the alarm volume is adapted to the patient environment.	☐ Pass
9	Ensure that you know how to charge the internal battery. Refer to chapter 6, "Internal Battery".	☐ Pass

Table B-1. Operational Verification Checklist (Continued)

10	Verify that the preventive maintenance schedule for the ventilator is followed.	☐ Pass
11	Ensure the patient breathing circuit is correctly attached to the ventilator, with all the necessary components, and is free from any signs of damage and leaks. If exhaled volume monitoring is required, use the double-limb circuit for exhaled tidal volume or minute volume monitoring.	☐ Pass

C Unpacking and Preparation

The Puritan Bennett 540™ Ventilator is shipped from the factory with the following items:

(1) Printed User's Manual

(1) Clinician's Manual on CD (a print copy is available upon request by the customer)

(1) Patient circuit and valve in one of the following configurations (as requested by the customer):

- Adult Single Limb
- Adult Double Limb
- Pediatric Single Limb
- Pediatric Double Limb

(1) Set of six (6) combination foam/fine particle air inlet filters

(1) Dual bag

(1) Oxygen connector

(1) AC power cable (US version)

WARNING

- **Users must always possess an additional breathing circuit and valve while using the Puritan Bennett 540™ Ventilator.**
- **To minimize the risk of damage, you must use the Dual Bag (part no. 2967200) to transport the**
- **Puritan Bennett 540™ Ventilator.**

To unpack and prepare the ventilator, follow the steps below.

1. From the plastic bag, remove the following:
   - Plastic pocket containing the User's and Clinician's Manual.
   - The ventilator and its components and/or accessories6.
2. Remove the patient circuit, the AC ("Mains") power cable, and the set of fine-particle air inlet filters (see Figure C-1).
3. Inspect the ventilator and ensure that:
   - the ventilator's outer casing and the **I/O** switch's protective cover do not have any dents or scratches, which may indicate possible damage.
   - the ventilator's labels and markings are clear and legible.
   - the AC power cable does exhibit any signs of damage, such as kinks, breaks, or cuts.

WARNING

Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your equipment supplier or Puritan Bennett.

5. Clean the ventilator with a mild soap solution, if necessary (refer to chapter 7, "Cleaning").
6. Ensure that the air inlet filter is installed.

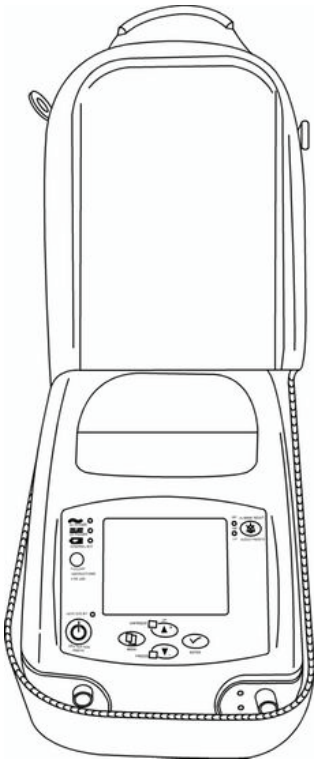

Figure C-1. Puritan Bennett 540™ Portable Ventilator

Figure C-2. Dual Bag

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D Modes and Breath Types

D.1 Modes of Ventilation

This chapter is a general description of the various modes of ventilation and breath types available with the Puritan Bennett 540™ Ventilator.

Note:

The default ventilation mode setting is PRES A/C; for more information, see below.

D.1.1 Assist/Control (A/C) Modes

When set to an Assist/Control mode, machine-initiated breaths are delivered at a clinician-set volume or pressure, inspiratory time, and rate. If the patient triggers a spontaneous breath between machine breaths, the ventilator will deliver a breath based on the volume or pressure settings and inspiratory time.

Whether initiated by the patient or the ventilator, all breaths are delivered at the same preset volume or pressure and inspiratory time.

The names of the Assist/Control modes are:

- VOL A/C, if the breaths are based on a volume setting
- PRES A/C, if the breaths are based on a pressure setting

D.1.2 SIMV Modes

When set to a SIMV (Synchronized Intermittent Mandatory Ventilation) Mode, machine-initiated breaths are delivered at a clinician-set volume or pressure, inspiratory time, and rate. These mandatory breaths are synchronized with patient effort. If the patient triggers a spontaneous breath between machine breaths, the ventilator will deliver a spontaneous breath, which is pressure-supported.

CPAP spontaneous breaths are not available in SIMV modes.

The names of the SIMV modes are:

- V SIMV, if mandatory breaths are based on a volume setting
- P SIMV, if mandatory breaths are based on a pressure setting

D.1.3 CPAP Mode

In CPAP, the ventilator maintains a constant level of pressure in the patient's airway. If your clinician has prescribed CPAP, you should talk to him or her for a further explanation of how CPAP operates.

D.1.4 PSV/CPAP Mode

Like CPAP mode, PSV/CPAP mode maintains a constant level of pressure in the patient's airway. In addition, the ventilator applies a clinician-set pressure (Pressure Support) to each of the patient's breaths. This has the same benefits as CPAP, with the additional benefit of assisting the patient in moving air into his or her lungs.

E Parts and Accessories

Table E-1 provides a list of accessories that are available for the Puritan Bennett 540™ Ventilator.

To order parts or accessories, contact your equipment supplier or Puritan Bennett representative.

Note: The ventilator is shipped from the factory with the following items: a printed User's Manual; a CD with Clinician's Manual (printed copy available upon request); one patient circuit with valve; one set of six (6) combination foam/fine particle air inlet filters; one dual bag; one O_2 connector; and one AC power cable (US version).

Table E-1. List of Consumables and Accessories

Description
Carrying bag (grey)
Oxygen inlet connector
Carrying belt
Suspension belt
Backpack Padded Straps
Remote Alarm Box and Cable
Ventilator Cart
Dual Bag delivered with: Backpack Padded Straps, 2 ea. Suspension belt Carrying belt **WARNING** **To minimize the risk of damage, you must use the ventilator Dual Bag to transport the ventilator.**
AC (mains) power cable
DC power cable (for connection to an external DC power source, such as a car cigarette lighter)
Remote alarm cable (5 meters)
USB cable, mini B
Exhalation block, single-patient use (blue)
Inlet air combi-filter, fine (pack of 6) **Note:** This is the "foam plus fine particle" filter listed in Table 8-1, Consumables and Replacement Intervals, on page 8-2).
Internal battery
External battery

Table E-1. List of Consumables and Accessories

Description
DAR™ Inspiratory Bacteria Filters
Barrierbac
Barrierbac S
Barrierbac S Angled
Hygrobac
Hygrobac S
Hygrobac S Angled
Hygroboy
Hygroster
Hygroster Mini
Sterivent
Sterivent S
Sterivent Mini
Hygrolife II

Table E-2 provides a list of consumable parts available for the ventilator.

WARNING

- **To ensure proper performance of the ventilator, use a patient circuit recommended by Puritan Bennett in this manual; refer to chapter 4, "Installation and Assembly". The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 3.6 feet (1.10 meters) to 6.6 feet (2.00 meters).**
  The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.

Table E-2. List of Circuits

Description	Part Number
Double limb patient circuit with exhalation valve, 180 cm, PVC, sterile, ADULT	5094000
Double limb patient circuit with exhalation valve, 180 cm, PVC, sterile, PEDIATRIC	5093900
Single limb patient circuit with exhalation valve, 180 cm, PVC, sterile, ADULT	5093600
Single limb patient circuit with exhalation valve, 180 cm, PVC, sterile, PEDIATRIC	5093500
Hudson™ single limb patient circuit, ADULT	1696
Hudson™ double limb patient circuit, ADULT	690-50
Allegiance™/Cardinal™/Airlife™ single limb patient circuit, ADULT	6463-H08

Hudson™, Allegiance™, Cardinal™, and Airlife™ are the property of their respective owners.

For more information regarding parts and accessories for the Puritan Bennett 540™ Ventilator contact your service representative or www.puritanbennett.com.

F Glossary

AC Power

Alternating current.

Alarm Pause

The audible and visual alarms cease and the symbol appears. The symbol will remain until the cause of the alarm is addressed. For example, when the ventilator is running on internal battery, the AC Disconnection alarm may be paused, and the alarm paused symbol will appear until the device is plugged into AC. The paused alarm will be captured in the alarm log screen and can be reactivated.

Alarm Reset

Used only for the High Pressure alarm, this function resets the visual alarm message.

Apnea

The absence of breathing or a breathing pattern capable of supporting an individual's respiratory needs.

Apnea Time

Time allowed between breath starts before APNEA alarm occurs when no patient effort is detected.

Assist/Control

In Assist/Control mode, the ventilator delivers an assisted breath of a set volume or set pressure when the patient's breathing effort creates a flow or pressure drop that is greater than the SENSITIVITY setting. In absence of patient breathing effort, the ventilator will deliver a controlled breath of the set volume or pressure. (Does not apply in PSV/CPAP mode).

Assisted breath

A volume or pressure breath triggered by the patient but then controlled and terminated by the ventilator.

Audio Pause

Pauses the audible alarm for 60 seconds at a time and shows the symbol; often referred to as "Alarm Silence."

Back Up Rate

Rate of control cycles in PSV or SIMV modes during apnea phase.

Battery Level

Display of the remaining battery capacity; located adjacent to the battery symbol.

Bias flow

Turbine flow during exhalation phase through the patient circuit to avoid rebreathing.

bpm

An abbreviation for "breaths per minute," which is the unit of measure for breath rate (see below).

Breath Rate

The total number of breaths, both machine and spontaneous, delivered by a ventilator in one minute.

Caregiver

An individual who assists a patient with the tasks of daily living. This may be a family member, a live-in assistant, or the nursing staff of a health care facility.

cmH_2O

An abbreviation for "centimeters of water," which is a unit of measure for pressure.

Continuous Positive Airway Pressure (CPAP)

Continuous airway pressure maintained throughout a spontaneous breath cycle.

Controlled breath

A volume or pressure breath triggered, controlled and terminated by the ventilator.

Double Limb patient circuit

Patient circuit with a tube between the ventilator gas outlet and the patient for inspiratory gas and another tube between the patient and the expiratory block for expiratory gas.

Exhalation block

Part of the ventilator that allows the connection of the exhalation limb of the patient circuit. The exhalation block is for single-patient use only.

Exhalation phase

Phase of the breath cycle during which the patient exhales.

Exhaled Tidal Volume (VTE)

Exhaled volume measured for all breath types through the exhalation block. Monitored value available only with double limb patient circuit.

Expiratory minute volume (Min VE)

Volume exhaled by the patient at each expiratory phase and multiplied times the respiratory rate.

Exhalation sensitivity

The exhalation sensitivity (Exh Sens) level is a percentage of peak flow at which a pressure-supported breath will be terminated.

Expiratory Tidal Volume (VTI)

Volume exhaled by the patient at each expiratory phase.

Flow

Volume of gas delivered by the ventilator compared to time, expressed in liters per minute (lpm).

Freeze

Interruption of the waveform plot tracing on the ventilator's display.

I:E ratio

Inspiratory time versus exhalation time ratio.

Inspiratory minute volume (Min VI)

Volume delivered to the patient at each inspiratory phase and multiplied times the respiratory rate.

Inspiratory Phase

Phase of the breath cycle during which the patient inspires.

Inspiratory Sensitivity

Level of inspiratory effort the patient has to provide during the initiation of a machine breath. The sensitivity levels (from 1 to 5) correspond to differences in flow compared to the bias flow. The level 1 is the most sensitive (for a pediatric use) and requires the least effort to trigger breath. The level 5 requires the most amount of effort to trigger a breath.

Inspiratory Tidal Volume (VTI)

Volume delivered to the patient at each inspiratory phase.

I Time

Inspiratory time measure.

L

Liters (a unit of volume).

LED

Light Emitting Diode; used as indicator lights on the ventilator's front panel.

lpm

Liters Per Minute (a unit of volume flow rate).

Machine Hours

Counter for the total ventilation time since manufacture or the last CPU board change.

Mains

AC power supply.

MAP

Mean Airway Pressure. Average pressure during a ventilation cycle.

Minimum Exhalation Time

Minimum exhalation time before allowing the patient inspiratory trigger.

Minimum Inspiratory Time

Minimum inspiratory time before allowing the patient to exhale.

Minute Volume

Minute Volume represents the total amount of gas volume moved into the lungs over a 60 second period. It is calculated by multiplying the average breath-to-breath inspired gas volume (Tidal Volume in liters or milliliters) by the respiratory rate (in breaths per minute). Minute volume is usually expressed in Liters per minute and is a better reflection of the patient's total ventilation status than either respiratory rate or tidal volume alone.

Pause

Waveforms freezing function.

Patient Breath

Breathing cycle initiated by the patient.

Patient Counter

Counter of ventilation time for the patient.

Patient effort

Inspiratory effort initiated by the patient.

Patient circuit

Tubing between the ventilator and the patient.

Peak Inspiratory Pressure (PIP)

The highest pressure measured in the patient circuit during the inspiration phase.

Positive End Expiratory Pressure (PEEP)

Pressure in the patient circuit at the end of expiration.

Pressure Control

Augmentation of the patient's ventilation synchronously with inspiratory effort until a preset pressure is met. Pressure is maintained throughout patient inspiratory flow, and is cycled to expiration by time (controlled by the selected Inspiratory Time setting). Used in Assist/Control mode.

Pressure Support

Augmentation of the patient’s ventilation synchronously with inspiratory effort until a preset pressure is met. Pressure is maintained until inspiratory flow is reduced to a percentage of peak flow that depends on the expiratory sensitivity setting for the inspiration, when the ventilator cycles into exhalation. Available in SIMV or Spontaneous modes.

PSI

Pounds Per Square Inch.

Rebreathing

The patient breathes his/her exhaled gas.

Respiration rate

The number of breath cycles (inspiration + expiration) completed within one minute. Normal resting adult respiratory rates are from 16 – 20 breaths per minute (bpm).

Rtot

Parameter measured by the ventilator equal to the total number of breaths per minute (bpm).

Volume breath

Inspiration of the selected volume, delivered over the selected inspiratory time.

Sensitivity

This adjustable parameter determines the amount of inspiratory effort required by the patient before the ventilator delivers an assisted breath, or demands flow in the case of a spontaneous breath.

The Puritan Bennett 540™ Ventilator is flow-triggered, with sensitivity levels in the range from 1 to 5: the lower the number, the more sensitive the trigger.

Spontaneous

A ventilation mode that delivers assisted breaths only. Spontaneous mode does not provide breaths if the patient does not make an inspiratory effort greater than the sensitivity settings and there is no apnea backup rate.

Standby

The operational mode of the ventilator where it is powered (power supply **I/O** button set to the **I** position), but is not ventilating the patient.

Synchronous Intermittent Mandatory Ventilation (SIMV)

A ventilator mode which provides a mechanism for synchronizing the ventilator-delivered breaths with a patient's inspiration, as detected by the ventilator.

Tidal volume (Vt)

Volume of gas delivered to the patient in a breath.

Unfreeze

Resumption of the waveform plot tracing on the ventilator's display.

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